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Role of MRI in Post Traumatic Stable Vertebral Fracture to Diagnose Spinal Injury – A Cross Sectional Study

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ABSTRACT

Vertebral fracture can be caused by direct or indirect trauma and are more likely to occur in patients with decrease bone density (osteoporosis, bony metastases). It aimed of studying characteristic imaging findings, to evaluate the role of MRI in patients with post traumatic stable vertebral fracture. All patients with history of post trauma were subjected to MRI examination. As MRI is the investigation of choice for soft tissue and spinal cord injuries. To ascertain the role of MRI in diagnosis of the spinal cord injury in cases of post traumatic stable vertebral fracture. It is a Hospital based Cross sectional study. A total of 119 Cases of spinal trauma who underwent MRI of the spine are included in the study. The Study was conducted in department of radiology over the duration of 18 months. All detailed history of patients was taken. The study has been done using 1.5 TESLA Siemens. Out of 119 cases, majority of the cases were >60 yr with male predominance. Post trauma [45 cases (37.8%)] was most common cause of injury among the cases and cervical spine [14 cases (28%)] was most common sites. MRI findings helped in detecting in spinal cord injury and soft tissue injury [50 cases (42%)]. Most common MRI findings were spinal canal Stenosis [73 cases (61.3%)], marrow edema [51 cases (42.9%)], spinal cord injury [50 cases (40.0%)], pre & paravertebral collection [14 cases (11.8%)], and IVD injury [5 cases (4.2%)]. Being a non-invasive procedure with high specificity and sensitivity, MRI is a preferred diagnostic tool to assess spinal cord injuries.

KEY WORDS: spinal injury, magnetic resonance imaging (MRI)

INTRODUCTION:

Vertebral fractures have a variety of etiologies including trauma, osteoporosis or neoplasm. An osteoporotic compression fracture has high prevalence among postmenopausal women and occurs less frequently in similar aged men^[1]. The young population is frequently involved in road accident, and incidence of fall from height. Spinal injury present in various severity & prognosis varying from asymptomatic condition to neurological deficit. Radiological imaging has important role in the management of spinal cord. MRI has been playing an important role in spinal injury due to specificity and sensitivity for detection of cord and soft tissue injury. MRI is first choice of investigation for evaluating the ligament and other soft tissue structures eg. Inter vertebral disc, spinal cord and occult osseous lesion.

Prompt and proper management of the patients with trauma from diagnosis to therapy can limit the neurological damage. A vertebral fracture is evidenced by vertebral body deformity or reduction in height of vertebral height beyond a certain threshold value in the absence of bone discontinuity. Vertebral fracture can be caused by direct or indirect trauma and are more likely to occur in patients with decreased bone density (osteoporosis, bony metastases). Fracture may be stable or unstable but there is a risk of damage to the spinal cord in case of stable fracture.

To Classify and describe vertebral fractures, vertebral morphology, reduction in height of vertebral body and location of fractures are consider. Osteoporotic fractures can be classified into three major types, depending on location of the fracture lines^[2].

Wedge fracture involving anterior (or less commonly posterior) edge of vertebral body. Concave or biconcave fractures, involving the central part of vertebra. Crush fracture, involving a combination of anterior, posterior and central elements. Types of the vertebral fractures:- vertebral compression fracture (m/c type); burst fracture; fracture – dislocation.

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Stability of the vertebral fractures: Stable – The structural stability of the spine remains intact. No neurologic deficits; Unstable – The structural stability of the spine is compromised. The spine can move as two or more independent units, which may cause spinal cord injury. Objective measurement of the vertebral deformity provides valuable information to the interpreting physician and helps grading fracture severity.

The goals of the diagnostic radiologist in spinal injury are to identify and correlate neurologic injury to vertebral fracture. There are some Imaging studies: Radiography - Plain radiographs are helpful in screening of fractures, but hairline fractures or non-displaced fractures may be difficult to detect; Computed tomography (CT) scanning - CT scans can readily detect bony fractures and help with the assessment of the extent of fractures; Magnetic resonance imaging (MRI) - This is usually the investigation of choice for determining the extent of damage to the spinal cord. MRI is the most sensitive tool for detecting lesions of neural tissue and bone.

Within each group, the deformity can be graded semi quantitatively according to the loss of vertebral body height.

Grade 0: normal/unfractured vertebra ; Grade I: vertebral body height is >75% of normal value; Grade II: vertebral body height is between 50 and 75% of normal value; Grade III: vertebral body height is < 50% of normal value. Even more important is to assess the deformity of the spinal canal and neural foramina. In spine fractures, the spinal canal is often narrowed from translation and intrusion of vertebral body fragments of vertebral body height.

MATERIALS & METHODS:

Ethics Proclamation: - All patients enrolled in this study were briefed about the nature and the course of study. Research Approval was obtained by Research Advisory Committee & Institutional Ethics Committee before the commencement of study.

Study Design/Study Type: - Hospital based Cross sectional study. Study Area & Source of Data: - The data for the study was collected from patients referred for MRI scan to the Department of Radiodiagnosis, People's College of Medical Sciences and Research Centre, Bhanpur, Bhopal (M.P.). Cases of spinal trauma who undergone MRI of the spine in the department were referred from various department of People's College of Medical sciences and Research Centre and People's Hospital, Bhanpur, Bhopal was included in the study. The study duration was

18 months from December 2018 to June 2020 and performed as per the standard protocol of MRI for spine.

Case Selection: The patients who were clinically suspected as a case of stable vertebral fracture were investigated with MRI. The study group had included a sample size of >100 patients selected by a purposive sampling. There are study variables:- Age; Gender, Site of injury; mode of injury; Risk factors; Radiologic findings; MRI findings; Disc involvement; Para spinal and soft tissue injury; Fractures; Spinal cord injury.

Inclusion criteria: Patient referred for MRI spine with stable vertebral fracture diagnosed by X-ray or CT scan; All the patients of acute spinal trauma undergoing MR Imaging form the study group.

Exclusion criteria: Patients who had poor GCS; with cardiac pace makers, cardiac defibrillators, ferromagnetic aneurysm clips; With cochlear implant, intra ocular metallic foreign body; Uncontrollable claustrophobia; Patients of spinal trauma undergoing MRI scan of spine after 2 weeks of injury and Diagnosed with unstable vertebral fracture.

Patient preparation procedure was briefly explained to the patient and consent was taken. Detailed history to rule out contraindication of MRI was specifically taken. Equipment study has been done using 1.5 TESLA Siemens Magnetom MRI. Standard surface coils and body coils were used for cervical, thoracic and lumbar spine for acquisition of images. Technique & Sequences, Patients were examined with MRI scan in the supine position with proper positioning and immobilization of the body, with quiet breathing and abdominal band compression. Standard surface coils were used for acquisition of images. Then images and report were collected & analyzed from MRI section of department.

MRI scanning was done using T1WI, T2WI, STIR sagittal, & GRE axial with slice thickness 4.5 mm x 5 mm. For spinal trauma contrast study was not done. Whenever required, thinner sections were obtained in the region of interest. A special MRI sequences like PD fat suppression and STIR were routinely obtained.

The MRI images were analyzed based on location (cervical, thoracic, lumbar & sacral), segment

of the spinal cord involvement, and severity of injury. In cases of trauma, site and level of injury, vertebral fracture, ligament injury, presence / absence of hematoma to classify into spinal subdural / extradural hematoma were noted. Follow up whenever possible patients were followed up and outcome recorded in cases of spinal trauma.

RESULTS:

This study is comprised on 119 patients who presented for an MRI scan of spine in the Department of Radio-diagnosis, People's College of Medical Sciences and Research Centre, People's University, Bhopal (M.P.) from December 2018 to May 2020 for the period of 18 months.

Those patients who fulfilled the inclusion criteria of stable vertebral fracture & associated with spinal injuries were enrolled in this study. Characterizations of the population and variables of recruited patient populations concerning different classifications are tabulated and graphically illustrate their distribution in different groups.

The present study designed as a cross-sectional observational study. Most of the variables used in our study are categorical in nature. Hence frequency and prevalence were calculated by Pearson's chi-square test also known as the Chi-square test for independence. A Chi-square test of association was also used to find if there was any relationship between two categorical variables.

The age of patients was between 10 to 87 years with a mean age of 46.4 years (Table 1). The majority were in the age group of >60 years (24.4%) followed by 31-40 years (28.8%), 51-60 Years (16.8%), 21-30 Years (12.6%), and <20 Years (10.1%).

The gender distributions among the patients

Table 1: Age Wise Distribution of Cases.

Age Groups	No. of Patients	%
<20 Years	12	10.1
21-30 Years	15	12.6
31-40 Years	26	21.8
41-50 Years	17	14.3
51-60 Years	20	16.8
>60 Years	29	24.4

were accordingly, Male (52.1%) and Female (47.9%) (Figure 1). Among the 119 patients in the study population group, the distribution of mode of injury is reported in (Table 2). Blunt trauma was found to be the most, majority with 45 (37.8%) cases. The other mode of injury were included in the descending order as fall from height 41 (34.5%), Road traffic accident 27 (22.7%), and Assault 6 (5.0%) respectively.

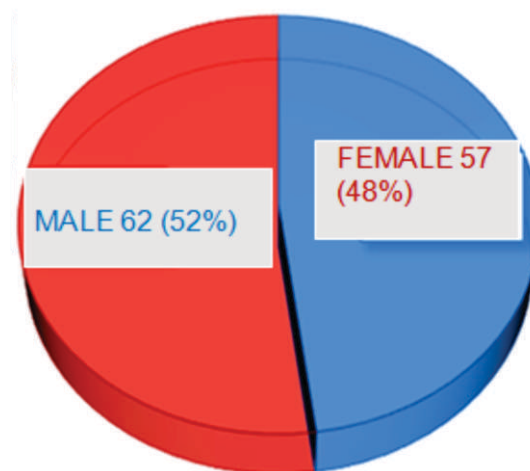


Figure 1: Distribution of Cases based on Gender.

Table 2: Distribution of Cases based on Mode of Injury.

Mode of injury	No. of Patients	%
Assault	6	5.0
Blunt Trauma	45	37.8
Fall From Height	41	34.5
Road Traffic Accident	27	22.7

All patients selected in the study had an X-ray and CT scan was 100% stable during the study. The study population was distributed based on spinal cord involvement which was diagnosed on MRI and it was present in 50 cases with 42.0% (Table 3).

The distributions of MRI findings among the study population were reported in graph 7. The vertebral fracture was accounted for in all cases 119 (100%) which was earlier diagnosed on either X-Ray or CT scan. The rest of the other findings were found as following in descending order of spinal canal stenosis 73 (61.3%), marrow edema 51 (42.9%), spinal cord injury 50 (42.0%), pre & para vertebral collection 14 (11.8%) and IVD injury 5 (4.2%) respectively (Figure 2).

Distribution of patients on the basis of involvement of spinal cord injury & level of injury

Table 3: Distribution of Cases on the Basis of Spinal Cord Involvement.

Spinal Cord Injury	No. of Patients	%
Absent	69	58.0
Present	50	42.0

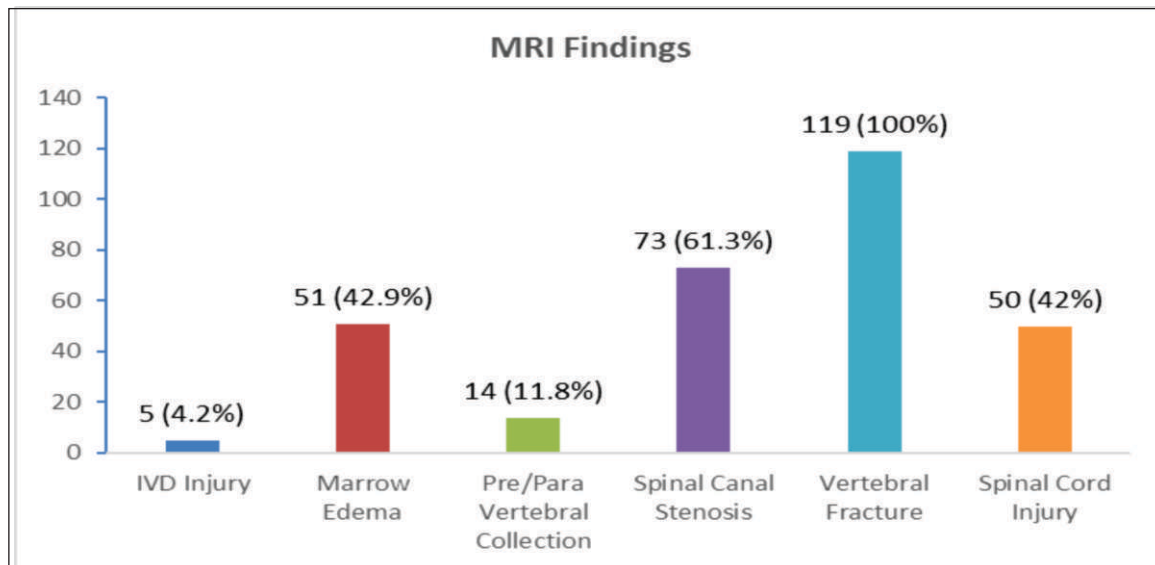
was reported in (Table 4). Spinal injury with the involvement of the Cervical cord was maximum 14 (28.0%) of cases. Other levels including with spinal cord injury had following order Lumbar 11 (22.0%), Dorsal 10 (20.0%), Dorsal & Lumbar 7 (14.0%), Sacral 2 (4.0%), Cervical and Lumbar 2 (4.0%), Cervical, Dorsal & Lumbar 1 (2.0%) respectively.

DISCUSSION:

MR imaging is one of the most important tools in the diagnosis of spinal injury and helps to start a prompt and correct treatment for patients. Compared to X-ray & CT scan, MRI allows better visualization of various tissues, including spinal cord and ligaments, not to mention discs and vessels. This study was done with the aim to ascertain the role of MRI in the diagnosis of the spinal cord injury in cases of post traumatic stable vertebral fracture.

STUDY DESIGN & POPULATION:

The present study design is cross sectional observational study. Most of the variables used in our study are categorical in nature. Hence frequency and prevalence was calculated. Compilation of raw data & statistical treatment of data was performed using MS Excel & Medical 19.5 software.

**Figure 2:** Distribution of Cases on the Basis of MRI findings**Table 4:** Comparison with other studies.

Studies	Mode of Injury							
	FFH	RTA	FOH	FOB	Physical Assault	Bullet injury	Bull Attack	
Hoque et al. ¹³	43%	18%	20%	-	-	-	-	
Islam MS et al. ¹⁴	50.5%	11.1%	15.2%	12.1%	-	-	-	
Razzak et al. ¹⁵	40.3%	14%	16%	9%	-	-	-	
Rahmanet al. ⁴	45.4%	25.9%	17.8%	-	-	1.8%		
Rahmanet al. ⁴	45.8%	24.7%	9.6%	9.0%	2%	0.7%	2%	
Moshiet al. ¹⁶	47.2%	62.8%	-	-	16.8	-	-	
Present study	34.5%	22.7%	37.8%	-	5.0%	-	-	

A total of 119 cases of spinal trauma who were undergone MRI of spine in the department of Radiodiagnosis referred from various department of People's College of Medical sciences and Research Centre and People's Hospital, Bhanpur, Bhopal were included in the study. The data were collected from December 2018 to May 2020 and performed as per the standard protocol of MRI for spine.

AGE & GENDER:

In our study, age of patients was between 10 to 87 years with a mean age of 46.4 years. The majority were in the age group of >60 years (24.4%) followed by 31-40 years (28.8%), 51-60 years (16.8%), 21-30 years (12.6%) and <20 years (10.1%). In the study by Rahman et. al, 56% of the patients were between 21 and 40 years of age and a study by Lenehan et al, reported 60% of the injuries in patients under 40 years of age. Nagvekar et al, reported 81% of the patients to be between 21-60 years of age^[4,5,6]. Similar results of other studies about mean age were reported as 47.44 years and 46.65 ± 16 years^[7,8] and not similar with Ulrich et al.'s study who found the mean age to be 36.1 years^[9].

As per Nalina et al,^[10] the commonly affected age group is 18–50 years and as per Flanders et al,^[11] the most commonly affected age group is 16-30 years. These observations by the above authors regarding the affected age group are close to our study.

The gender distributions among the patients were accordingly, male (52.1%) and female (47.9%). The most common gender affected was males in the present study. In a study by Rahman et al, the male to female ratio was 5:1, which was not found in accordance to this study. In a study by Nagvekar et al, 71% of the patients were males and a higher patient load of males was also seen in another study by Lenehan et al^[4,5,6].

Among the distribution of mode of injury, blunt trauma was found major portion in our study with 45 (37.8%) cases. The other mode of injury were had descending order as fall from height 41 (34.5%), road traffic accident 27 (22.7%) and assault 6 (5.0%). While comparing to a study done in Bangladesh was found quit concordant in which fall from height (45.8%) was the leading cause of spinal cord injury and road traffic accident whereas the second most common cause according to the study from 1995 to 2009^[2].

Various studies reported in literature were compared with our results and found similarity in mode of injury partially.

Spinal cord injury with involvement of Cervical spine was maximum 14 (28.0%) in cases. While at other level of involvement with spinal cord injury had following order: Lumbar 11 (22.0%), Dorsal 10 (20.0%), Dorsal & Lumbar 7 (14.0%), Sacral 2 (4.0%), Cervical and Lumbar 2 (4.0%), Cervical, Dorsal & Lumbar 1 (2.0%). In a study reported by Ning et al. they found that cervical region accounted for more than 54% of total cases, followed by thoracolumbar region for the level of injury of spinal cord injury. In another study cervical spine injuries 358 (40%) were the most common spine injuries, followed by lumbar, thoracic and sacral injuries^[13,14,15,16,17,18].

Comparing with other studies patients were distributed on the basis of spinal cord involvement and it was present in 50 cases with 42.0% involvement. While in a report it was observed as 43%^[19]. These observations by the above authors regarding the affecting spinal cord injury are close to our study. In another study level of injury among 57 patients, 43.86% had injury at cervical level followed by dorsal and lumbar levels 21.05% and finally, 14.04% had dorsolumbar injury^[20].

MRI is only imaging modality to assess spinal cord injury, to diagnose location and the severity of lesion and to detect extent of spinal cord compression and also helpful in detecting bone marrow edema.

Age & gender wise distribution of cases on the basis of mode of injury & spinal cord injury were also accounted. Maximum no. of cases was found for spinal cord injury in male was found for age group 31-40 Years 10 (32.3%) in road traffic accident and >60 years 8 (25.8%) in fall from height while in females maximum cases were observed in 50-60 yr age group 5 (26.3%) in fall from height. Such demonstrations were not found in any study and it was reported as total cases in male and female. In study of 57 patients underwent MRI for evaluation of spinal trauma with majority being males (86%) and young and middle aged men were the most common age group involved. Finally, it may be said no similar trend was observed in our study as reported in other studies with regards to MRI findings and with gender distribution^[20].

CONCLUSION:

Being a non-invasive procedure with high specificity and sensitivity, MRI is a preferred diagnostic tool to assess spinal column injuries & spinal cord injuries. We can identify gross osseous fractures, ligament disruption, soft tissue injuries with high precision and accuracy. However, it was difficult to identify the smaller posterior element fractures and incapacity of MRI in the case of patients with pacemakers and other implants. Despite its few disadvantages, MRI leads to provide prompt and accurate diagnosis, expeditious management, and avoidance of unnecessary procedures, thus, in the process of improving post-traumatic quality of life of patients of spinal trauma.

We conclude that spinal cord injuries are more common in males as compared to females and more common in the age group 21-60 years age group. Among all types of injuries like blunt trauma, fall from height is more common in males. The lumbar spine injury was found most common. The most common MRI findings in our study was Spinal Canal Stenosis followed by marrow edema and IVD injury was found in the least number. MR imaging is the only imaging modality to assess spinal cord injury, to diagnose the location and the severity of the lesion and to detect the cause of spinal cord compression. Moreover, the numbers of patients were limited in this study to accurately evaluate the effectivity of MRI in neurological prognosis.

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Determinants of mid-life Health Among Rural Women of Central India: A Cross-Sectional Study

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ABSTRACT

India has about 130 million women in menopausal age of which nearly half reside in rural locations. With the concentration of health care facilities in and around urban areas, attaining adequate mid-life health care in rural settings poses a distinct challenge. The role of primary care providers thus gains paramount significance in rural settings. An observational, cross-sectional study conducted at the rural district health centre of central India. All women above 40 years of age were offered voluntary participation. All health care providers were interviewed using a set questionnaire. Data recorded and analyzed to assess the awareness and attitudes towards menopausal health. Descriptive statistical analysis methods were used. Results: The mean age for all women was 56 years. Lack of education (56%), long distance from the facility (55%), poor economic conditions (95%) and late reporting (70%) were common challenges. Overall, menopausal awareness among nursing and medical officers was good but the practices of screening for other medical conditions lacked in many (70% and 40% respectively). Conclusions: Promoting education, regular training of medical and paramedical staff at the periphery, the building of health care facilities close to community levels, health promotional activities and policy amendments are key to improve mid-life health in rural settings.

KEY WORDS: menopause, rural women, mid-life health, paramedical staff

INTRODUCTION:

Menopause (defined as complete cessation of menstruation) forms a significant transitional phase in women's lives. It not only marks the transition from reproductive to nonreproductive phase but also accelerates the process of ageing and other medical disorders. Globally, there is an overall rise in average lifespan and women are spending as much as one-third of their lives post-menopause. As far as Indian women are concerned, the varied genetic and socio-demographic characteristics have led them to embark upon menopause at much earlier ages. At a stage when a woman is challenged by varied psychophysiological limitations of menopause, focussed and supportive attention by her healthcare provider gains paramount importance. Thus contact with her health care provider also serves as an important window of opportunity to offer screening of medical conditions common and prevalent at this stage of woman's life.

Illiteracy, diverse cultural beliefs, limited

socioeconomic resources, poor access to health care systems and poor patient motivation to seek health care commonly pose a distinct challenge to midlife health care provision in Indian rural settings. The current study was undertaken to study the various lacunae in menopausal health care in such a rural district of central India.

To study level of awareness about menopause among rural perimenopausal and postmenopausal women. To study awareness and attitude about menopause among nursing personals and general practitioners. To study the reasons of gap in midlife health.

MATERIALS & METHODS:

This was an observational, cross-sectional, questionnaire-based study conducted over a period of six months by the Department of Obstetrics and Gynaecology of a Government Medical College of Central India in 2019. All women above 40 years of age attending the Gynaecology outpatient department of a district health centre were offered voluntary participation in the study. A total of 65 menopausal and perimenopausal women above 40 years of age were enrolled. About 30 nursing personnel and 20 medical officers working at the district health centre were also offered voluntary participation. After detailed information and consent, the women were interviewed

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using a pre-determined questionnaire to study their level of awareness about various health problems associated with menopause. Various female nursing personnel and general practitioners involved in health care delivery at district hospital were also interviewed using separate sets of questionnaires. All participants were free to opt-out of the study at any point in time. The data were recorded in tabulated format and the study was carried out.

All women were interviewed for the common symptoms if any they experienced and the duration of their symptoms. The various reasons for a delay in seeking health care were also noted if any. Nursing personnel were interviewed for their awareness about menopause, its definition, common presenting signs and symptoms and common medical conditions that can be screened in women approaching menopause. The medical officers involved in giving primary care to these women were also interviewed for their awareness about menopause, common clinical presentations, medical diseases that can be screened in these women and primary care modalities that can be offered to these women.

RESULTS:

Out of 65 enrolled, sixty women completed their interview. Demographic details like age, parity, educational status, gross family income, approximate distance from the health care facility, duration of their menopause and common symptoms were noted. All women ranged between the age group of 40 to 68 years. The mean age of women was 56 years (Table 1). The majority were multiparous with only 2 were primipara. About 50% were uneducated while 36% had some primary level of education. Approximately 25% resided within 5 km of health facility while a majority (55%) reported from distant peripheral rural places more than 25kms from the health centre (Table 2). Often, they travelled three to four hours to reach the facility. Very few (10%) reported within the initial 3 years of final menstrual period with common complaints being vague abdominal discomfort or backache or generalised tiredness (Table 3). A majority (90%) reported with urogenital symptoms with long-standing, huge uterovaginal prolapse being the major complaint. Often these were chronically neglected cases with decubitus ulcers, mucosal atrophy and irreducible prolapse. Generalised body aches with the inability to perform day to day activities were reported by almost all but none of them was aware that it could be related to their declining ovarian function or menopausal status. Vasomotor symptoms and sexual dysfunction were admitted by only a few after direct

questioning (Figure 1). None of them was clear about sleep disturbances and declining mental functions. Almost all belonged to poor socioeconomic status (95%) and expressed an inability to procure medicines other than freely available government supplies. The commonly reported reasons for neglected care and late reporting were gross ignorance, illiteracy, financial issues and distance from the facility (Table 4 & Figure 2). Often the accompanying family persons were daily wage workers or only bread earners of the families, further compounding their problem.

Table 1: Showing Age Distribution of Menopausal women.

Age(in years)	Number	Percentage
40 - 50	03	5%
50 – 60	42	70%
60-70	15	25%
More than 70 years	Nil	-
Total (Range 40-68 yrs)		n = 60

Table 2: Showing Distance from the facility.

Distance from facility	Frequency (n = 60)	Percentage
< 5 KM	15	25%
5- 25 KM	12	20%
>25 KM	33	55%

Twenty medical officers and thirty nursing personnel were interviewed using a separate set of questionnaires only after they expressed willingness to participate in the study. Questions were asked regarding the definition of menopause, and common symptoms women experience during such transition, which common medical conditions can be screened during such contacts with health care providers and common management approach opted by them (only for medical officers) while treating women above forty years. About 75% of nurses could define menopause correctly while almost all medical officers (95%) were aware as to when to call menopause. Generalised body ache and fatigue were reported to them as the most common complaints by women followed by urogenital symptoms (pruritus, prolapse, dysuria, urinary tract infections, prolapse). Vasomotor symptoms were rarely reported while it was extremely difficult to elicit complaints regarding sexual dysfunction and cognitive decline. Only 60% correctly identified common medical conditions (hypertension, diabetes, osteoporosis, gynaecological malignancies, breast cancer, depression) that can be screened and picked up early by adopting careful vigilance. On enquiry into

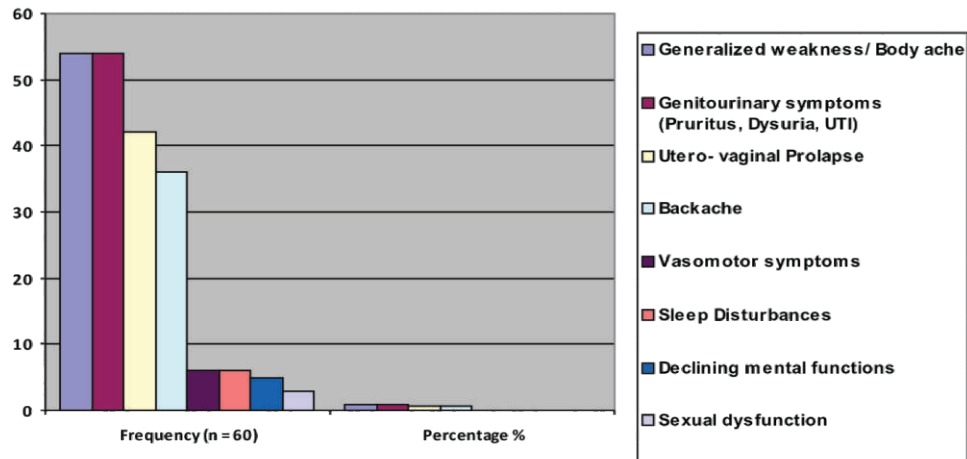


Figure 1: Showing common presenting symptoms.

Table 3: Showing common presenting symptoms.

common presenting symptoms	Frequency (n = 60)	Percentage %
Generalized weakness/ Body ache	54	90%
Genitourinary symptoms (Pruritus, Dysuria, UTI)	54	90%
Utero- vaginal Prolapse	42	70%
Backache	36	60%
Vasomotor symptoms	06	10%
Sleep Disturbances	06	10%
Declining mental functions	05	08%
Sexual dysfunction	03	05%

Table 4: Showing Reasons of late reporting.

Causes of late reporting	Frequency (n = 60)	Percentage
General Ignorance	52	70%
Illiteracy	35	60%
Distance from the facility	35	60%
Financial issues	35	60%
Lack of accompanying family persons	42	70%
Miscellaneous	06	10%

management options, 80% counselled women about lifestyle and dietary modifications, while 40% offered non-hormonal pharmacological and supportive treatments to their patients. None of them was prescribing HRT to any of their patients and would prefer to refer patients to specialist care (Table 3, 4 & 5; Figure 2).

DISCUSSION:

India's consistently growing economy has resulted in an overall rise in average life expectancy with 20% female population falling above the age of

45years.^[1] As per WHO (2018), the life expectancy of Indian female is expected to escalate from 70.3 years to 77 years by 2050.^[2] The literature of past has shown that Indian women by their characteristic genetic, ethnicity, socio-cultural and demographic features attain menopause much earlier (46 years) compared to Caucasians (51years) and thus spend near about three decades of their life post-menopause.^[3] Menopause, though simply defined as the permanent cessation of menses, for a majority of women it is an unfolding of many physical and psychological challenges and barely a smooth transition. WHO defines health as a

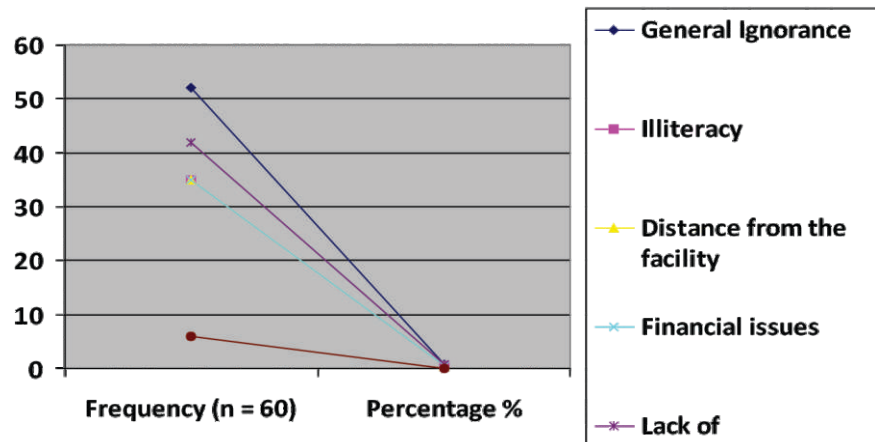


Figure 2: Showing reasons for late reporting.

Table 5: Showing Awareness and Attitude of Medical Officers and Nursing Staff.

Awareness and attitude of Medical Officers and Nursing Staff	Medical officers (n = 20)		Nursing Staff (n=30)	
Awareness about Menopause	19	95%	24	80%
Screen for common medical conditions (DM, HT, Osteoporosis, Gynecological Malignancy, Breast Cancer, Depression)	12	60%	18	60%
Counsel about lifestyle and Dietary Modifications	16	80%	12	40%
Offered Non – pharmacological treatment	08	40%	-	None
Offered Hormone therapy	Nil	None	-	None
Referred to gynecologist / othercenter	10	50%	27	90%

state of complete physical, mental and social well-being and not mere absence of disease or infirmity. ^[4] Holistic mid-life health for all women thus becomes an important health target to all health care providers.

Menopause or complete cessation of menstruation is a routine phenomenon for women across the world. But often, the physical and psychological experiences related to menopause are influenced by various socio-cultural practices, economic status, social development and family support received by women. ^[4] In our study the mean age of participants was 54 years (Range: 40-68yrs), almost all were multiparous (99%) and about one third received some primary level of education. Almost all belonged to poor socioeconomic status (95%). In a study by Khan et al, the mean age of participants was 58.14 yrs, with maximum belonged to the group 56-60 years and only 2.3% reporting during 40-45 years ^[1]. In the current study, about $\frac{3}{4}$ of women resided far off from the facility (> 25 km) and required some transport or family support to reach the health centre. In a study by Khan et al, the majority of the women in both rural and urban areas were unemployed or homemakers and

were dependent on their children ^[1]. A report by Government of India stated that among elderly women, about 70% women are dependent on their children, 20% depended on their spouses, 3% on grandchildren and more than 6% on others including the non-relations ^[5].

Biologically ageing ovaries with consequent drop in estrogen levels pose menopausal women to multiple sets of problems. Vasomotor symptoms (hot flashes, night sweats), urogenital dysfunctions, cognitive decline, sexual disorders, lack of energy (sarcopenia), backache, osteoporosis with increased risk of cardiovascular morbidity and genital and extra-genital malignancies are common accompaniments at this stage. Indian rural women, however often regard menopause as freedom from socio-cultural restrictions, reproductive burden and physical discomfort arising out of monthly menstrual bleeds. ^[1] Many grow old facing the adversity of gender discrimination, domestic violence, financial inequality and other domestic hardships often suffering in silence and keep neglecting their symptoms until they start affecting their day to day lives. ^[1] In our study, 70% of all women

were into menopause for more than ten years with only 10% reporting in the initial 3 years of menopause. Alizadeh et al reported that the experiences at menopause are influenced by awareness about menopause, age at menopause, education, employment, stress, environmental conditions, cultural norms, social factors and social communications related to menopause.^[6,7] In our study, urogenital symptoms with fatigue were most commonly (90%) reported symptoms.

Karmarkar et al opined that physical symptoms such as lack of energy occurred in 93% followed by aching in muscles or joints and difficulty sleeping in 84% while low backache in 69% of women.^[8] Ignorance about menopause (90%), poor socioeconomic status (95%), need of a person to accompany (80%) and distance from the facility (55%) were major factors responsible for poor healthcare-seeking behaviour, in our study.

India with a population of 1.2 billion, has about 10% population (100 million) aged over 50 years^[2]. The menopause in women labelled as a biomarker or escalated risk marker for common non-communicable diseases (hypertension, diabetes, CHD, stroke, osteoporosis, malignancies) also serves as an important window of opportunity to screen and initiate preventive and promotive health measures in women. Unfortunately, though the contact with health care worker or visit to the health facility in rural settings is rarely a health-seeking act towards their menopausal symptoms. More than often the consult is for unrelated health issues or only an opportunistic contact. In resource-limited settings and rural India where nursing personnel and general medical practitioners often form the primary backbone of health delivery system, it gains paramount significance that primary health care providers and nursing personnel be aware and able to provide adequate menopausal care to such women. In our study, we interviewed 30 nursing personnel and 20 general practitioners about their knowledge, attitude and practices towards menopausal women (Table 5). About 3/4th of nursing personnel and almost all (95%) medical officers could define menopause correctly. However, only 60% of medical practitioners and 30% of nursing personnel knew that these women can also be screened for other medical conditions common in such women. Though 80% of medical practitioners were utilizing the opportunity for dietary and life-style counselling only 40% were prescribing non-hormonal medications. None of the nurses or medical doctors was using the opportunity to screen such women for malignancy common at this stage such as breast and

cervical malignancy. In their study, Umakant et al concluded that most of the paramedical staff lacked knowledge about menopause including HRT and often considered menopause as natural phenomenon rarely requiring any medical assistance^[9]. About two-thirds of the Indian population resides in the rural area of which approximately half are females. As per reports, 130 million women in India are in menopausal age further emphasising the need to strengthen primary preventive and promotive mid-life health at community levels close to the women residing in peripheral areas^[10].

CONCLUSION:

Midlife health among rural women contributes significantly to the overall health status of the nation. Spreading awareness, promoting healthcare-seeking behaviours among such women through public awareness camps, incorporation of media, policies amendments and involving health care workers at grass root level in providing menopausal care would help in promoting the overall health of the nation and would bring about a reduction in mortality and morbidity of non-communicable and malignant diseases associated with menopausal status.

LIMITATIONS OF THE STUDY:

Most of the questions were answered using the recall method. Larger population-based studies may be warranted to reflect true status in general population.

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Complete Denture Impression Procedures and Techniques Performed by Dentists in Madhya Pradesh : A Survey

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ABSTRACT

The aim of this study was to identify the attitude and practices of dentists towards impression procedures in complete denture fabrication. For this purpose 18 self-designed close ended questionnaire survey form were prepared. Ethical clearance was taken from the institute and only those the participants who had submitted the response were included in the survey. 500 questionnaires were distributed at Indore city and only 100 were analyzed, 400 responses were disqualified as participants did not attempt all the questions or participants had marked more than one answer. It was found that about 10% of practitioners claimed that they fabricate complete denture. Majority of responses; about 96% reported that they perform both primary and final impression for complete denture. For making primary impression 75% of practitioners used impression compound. All the practitioners responded positively for making final impression with custom trays. For fabricating custom tray, 60% used self-cured acrylic resin. 84% used Selective pressure impression technique for taking final impression. The survey concluded that the historic concepts of impression making still hold importance and practitioners still use the trends established long back.

KEY WORDS: complete denture, impression material, impression technique, practitioners.

INTRODUCTION:

Fabrication of complete dentures include various steps that include primary impression making, border moulding, final impression, laboratory procedures, jaw relation, teeth selection, teeth arrangement, try in stage and denture insertion. Accuracy in the fitting of the denture is achieved only if all the procedures are performed properly. However, dentists have their own level of convenience in performing the procedures. The interns, who are in the final year of the dental undergraduate course are expected to have enough competence to proceed with their private practice. This level of competence can be evaluated based on the perception of interns about themselves in performing various dental procedures. Also, these kinds of studies may reveal the strength and weakness of the education system itself since

student reviews are the most essential component of monitoring the quality of education^[1].

Many dental graduates who move overseas find it difficult to face the clinical tests and other tests for entry into the institution^[2].

The possible reason for this being the low levels of competence with respect to the field of work. For facing the current scenario, a learning system that takes the students towards achieving competence is needed and evidence based learning is practiced popularly worldwide. Combination of knowledge and attitudes with reliable performance in natural settings without assistance is what makes a graduate competent. When the students attain enough competency, it incorporates in them a positive attitude and confidence to work independently^[3].

Literature reveals that dentists are the main source of information for the patients^[4].

So, it is essential that the dentist has a thorough knowledge about the procedures. This study evaluates the level of confidence of dental interns in performing each of these procedures through a questionnaire. The study also evaluates the knowledge about the materials involved.

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MATERIALS & METHODS:

The study was conducted in the Department of Prosthodontics of RKDF Dental College and Research Centre after taking approval from the institutional Ethical Committee. The study population included dentists practicing in Madhya Pradesh. The online questionnaire was used for collection of data. The sample size calculated was 100.

The questionnaire had 18 questions that would reveal the attitude and practice of dentists towards the preparation of complete denture. The questions were arranged in order of the steps involved in complete denture fabrication. The questionnaire was mailed via google forms to interns from various colleges in Madhya Pradesh. Question papers were mailed to about 500 interns, and the first 100 completed question papers were used for research. The collected data was tabulated, and analyzed using the Statistical Package for Social Sciences software, SPSS version 22.0 (IBM Corporation, Statistical Package for the Social Sciences. N.Y., USA).

RESULTS:

The results stated that about 100% of practitioners claimed that they fabricate complete denture. Majority of responses; about 96% reported performing both primary and final impression for complete denture. For making primary impression 75% of practitioners used impression compound, 24% used alginate impression material. All the practitioners responded positively for making final impression with custom trays. For fabricating custom tray, 60% used self-cured acrylic resin, 38% used shellac base plate and 2% used light cured resin. 70% participants preferred to fabricate custom trays few hours before the procedure and 30% preferred few days before the procedure to avoid warpage. Regarding the spacer design 70 % used full spacer with tissue stops. Most common material for spacer was base plate wax (70%) followed by spacer wax (25%). The preferred type of handle design by 56% of the practitioners was L- shaped. All the participants responded positively for border moulding. The border moulding material used by 77% was low fusing impression compound while 23% used putty (rubber base material). 84% used Selective pressure impression technique, 15% followed mucostatic technique and 1% used muco- compressive technique. For making final impressions 73 % uses ZnO-E or non Eugenol pastes. For the disinfection of the impression 43% used lutaraldehyde as the disinfectant for impression.

DISCUSSION:

This survey was conducted to relate the theoretical procedures of impression making in complete dentures with the trends followed in clinical practice nowadays. In this survey, every practitioner responded positively for complete denture fabrication. This trend suggested that the complete denture fabrication which was an age old form of treatment, still the preferred treatment of choice for completely edentulous ridges^[5,6].

Majority of the dentists performed both primary and final impression for complete denture fabrication. These results were supporting the previous surveys^[5,7]. The most commonly used preliminary impression material in this survey was impression compound (75%); irreversible hydrocolloid was used by only 24% respondents. This is consistent with the result of past surveys^[5,7].

However, there has been decline in its use in primary impression due to difficulties in handling and unreliable sterilization in case of reuse. This result does not match with another surveys, carried out in other four major cities of India (which concluded that a majority (71%) use alginate for preliminary impressions^[6]) and survey from UK, US and Turkish dental school (use of alginate as the primary impression material of choice^[8-10]).

100% practitioners responded positively for making final impression with custom trays. This was in agreement with previous surveys^[5,7,8,10,11]. The choice of material for making custom tray is cold cure acrylic resin. The special tray should be rigid and dimensionally stable. In similar surveys in US of prosthodontists and dental schools, almost all use custom trays made up of cold cure^[5,6]. The survey conducted in US, showed 70% of dentist used VLC trays for final impression^[9]. Visible light cured acrylic resin has lower residual monomer content, improved flexural strength and fracture toughness and offer advantages of rigidity, biocompatibility, accuracy and easy fabrication over cold cured trays^[12].

There was preference [70%] to fabricate custom trays a few hours before the procedure. This statement was in agreement with Gujarat survey^[5].

This was in contrast with previous U. S. survey, where 73% respondents fabricated custom trays few days before the procedure to prevent distortion by polymerisation shrinkage^[9].

Tissue stops helped in proper vertical orientation of the tray and maintained the thickness of impression material. This result was supported by many authors^[13,14].

Question	Responses	Percentage
Do you normally fabricate complete denture or not?	Yes	100
	No	0
Do you perform both preliminary and final impression for complete denture prosthodontics?	Yes	96
	No	0
	Not always	4
What material do you use for making primary impression?	Impression compound	75
	Irreversible hydrocolloid(alginate)	24
	Impression compound and Irreversible hydrocolloid	0
	Any other materials	1
Do you use special trays for making final impression?	Yes	100
	No	0
What is the tray material you normally used?	Shellac base plate	2
	Self-cure acrylic resin	60
	Light cure acrylic resin	38
	Any other material	0
When to fabricate custom trays to avoid warpage?	Few days before the procedure	70
	Few hours before procedure	30
	Any other	0
What spacer design do you prefer?	Full spacer with tissue stops	70
	Full spacer without tissue stops	20
	Any other design	10
Which material do you use for spacer in special tray?	Spacer wax	25
	Base plate wax	70
	Any other	5
How much relief do you normally provide in a special tray?	One layer of spacer wax	56
	Two layers of wax	44
	Relief only in undercut areas	3
	No relief	1
Do you specify your technician regarding handle design of special tray?	Yes	66
	No	34
What type of handle design do you prefer?	L- shaped	56
	Stub shaped in centre	36
	Stub in premolar region	8
Do you regularly do border moulding?	Yes	100
	No	0
What material do you prefer in border moulding?	Low fusing impression compound	77
	Polysulfide	0
	Polyvinyl siloxane	0
	Polyether	0
	Any other material	23 Putty
Which impression technique do you follow regularly?	Mucocompressive technique	84
	Mucostatic technique	15
	Selective pressure technique	1
	Zinc oxide Eugenol impression paste	73
Which impression material do you prefer for making final impression?	Light body elastomeric material	19
	Any other	8
	1-2	52
What are the number of escape holes do you make in custom tray?	2-3	27
	3-4	21
Do you disinfect your impression?	Yes	61
	No	39
What disinfectant do you use normally?	Alcohol	8
	Glutaraldehyde	43
	Sodium Hypochlorite	18
	Any other	31 (Tap water)

For spacer material results were constant with U.S. survey where they preferred base plate wax as a spacer material in custom tray^[15]. Results were similar with previous clinical reviews^[13,16,17].

The selective pressure impression philosophy predominantly used for making of final impressions. This theory was based on the anatomical differences and load bearing capabilities of the underlying structures. Previous surveys have shown the similar findings^[4,5,7,8,10,12,13,16,18,38].

For the final impression materials the results were constant with previous surveys where final impression was recorded with a wash material like ZOE paste or non eugenol impression paste. Light body elastomer can also be used^[5,7,10,18]. For the disinfection of the impression, majority were responded positively and coincided with Alqattan WA^[12], Vohra Fet al^[6] and Ferreira FM et al^[9].

CONCLUSION:

The present survey concluded that complete denture prosthesis is fabricated by most of the practitioners. Most of the practitioners are making primary and final impressions. The impression compound is the material of choice for making primary impression. All the participants are making final impression with custom tray made up of self-cure acrylic resin. Full spacer with tissue stops design is preferred using one layer of base plate wax. Border molding and Selective pressure impression technique followed by majority of practitioners for making final impression using zinc oxide Eugenol impression paste.

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Evaluation of Cephalometric Norms for COGS Analysis in Bhopal Population

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ABSTRACT

Cephalometrics for Orthognathic Surgery (COGS) parameters of hard and soft tissue of one state population in India cannot be applied to another group. So, it becomes necessary to understand the cephalometric norms in populations of different state. The aim of the study was to determine the hard tissue cephalometric norms for orthodontic sequency applicable to the population of Madhya Pradesh using HP plane as reference plane. The study was conducted in Department of Orthodontics and Dentofacial Orthopaedics, Mansarovar Dental College, Hospital and Research Centre, Bhopal. The present analysis was made on lateral cephalograms. Horizontal Plane (HP) is used as base line for comparison of most of data in this analysis. The cephalometric norms for orthognathic surgery were done on 130 Class I patients. The mean value for the COGS analysis was significantly different from the normal. There were significant difference in the COGS value for both males and females. These values were recommended for use in the orthognathic surgery done on the central Indian population. The cephalometric norms for orthognathic surgery found in the study done on central Indian population were significantly different than the norm of the Caucasian population. The norms for the Indian population are taken into account during orthognathic treatment planning.

KEY WORDS: orthogenetic surgery, cephalometric norms, burrstone analysis

INTRODUCTION:

Facial harmony and balance are maintained by the facial skeleton and its overlying soft tissue. Orthodontic diagnosis and treatment planning are based on the evaluation of the patient's soft tissue profile^[1]. Lateral cephalometric radiograph is an extremely useful diagnostic tool in orthodontic practice. It was introduced in 1931 by Broadbent Cephalometrics. It is the most commonly used clinical tool for evaluating jaw relationships in all the three planes that is sagittal, transverse and vertical planes. In modern day practice, the treatment goal for any patient that requires combined orthodontic treatment and orthognathic surgery are determined systematically through cephalometrics, the importance of which can be elaborated as follows: 1.

Cephalometric analysis aid in diagnosis of skeletal and dental problems; 2. It can help simulate orthognathic surgery through 'Surgical Treatment Objective' (STO) and 3. It allows the clinician to evaluate the changes following the completion of the treatment.

At present, a large number of adults-seeking orthodontic treatment require orthognathic surgery. For successful treatment of orthognathic surgery, accurate diagnosis of facial, skeletal, and dental problems is a must. For this reason, a specialized cephalometric appraisal system called Cephalometrics for Orthognathic Surgery analysis (COGS) concerning the hard tissue and soft tissue of the face had been developed by Burstone et al^[2].

Cephalometrics for Orthognathic Surgery (COGS) was developed at University of Connecticut in 1978. It has the characteristics which makes it particularly adaptable for the evaluation of surgical orthognathic problems.

The COGS system describes the horizontal and vertical position of facial bones by use of a constant coordinate system that includes various linear and angular measurements which are measured

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either parallel or perpendicular to true horizontal plane (HP). This HP can correct arbitrary nature of reference planes (SN and FH) used in other analysis that also vary just as the landmarks in maxilla and mandible that are related to them. Another advantage offered by this analysis is that it is based on the landmarks that can be altered by various surgical procedures. Various rectilinear measurements describe the discrepancy in critical skeletal components that can be readily transferred to acetate overlay and study casts for detailed planning of treatment and post surgical evaluation.

The values of COGS analysis proved to be very useful as they are based largely on rectilinear measurements that can be used during surgery for prediction overlays, mock surgery, and may serve as a basis for the assessment of post-treatment stability. These analyses have been extensively used for research studie^[3].

However, all these studies were carried out in Caucasians based on sample populations of European-American ancestries whose reference value may not be applicable to other ethnic types. For this reason, attempts have been made to investigate the differences of the human face among various ethnic groups including Africans^[4] African-Americans^[4] Chinese^[5] oreans^[6] Saudi Arabians^[7] Mexican-Americans^[8] Puerto Ricans^[9].

The skeletal, dental, as well as soft tissue variations exist in different groups of population. India is a large country with around 15 % of the world population. The cephalometric parameters of hard and soft tissue of one state population cannot be applied to another group. So, it becomes necessary to understand the cephalometric norms for different populations. Thus, the present study was conducted to determine the norms of cephalometrics for orthognathic surgery (COGS) in the population of Bhopal (MP).

MATERIALS & METHODS:

The present cross-sectional study was conducted in Department of Orthodontics and Dentofacial Orthopaedics of Mansarovar Dental College, Bhopal.

Study Population:

The study population comprised of patients having age group of 18 - 40 years having Class I molar relationship with aesthically pleasant profile not gone for any orthodontic treatment previously.

Approval from Authorities : The study protocol had got approval from Institutional Ethical Committee of Mansarovar Dental College, Bhopal.

Training and Calibration of Examiner: A single examiner performed all the examinations throughout the study. The investigator was trained and calibrated in the Department of Orthodontics and Dentofacial Orthopaedics in order to minimize the diagnostic variability.

Inclusion Criteria: Patients between 18 to 40 years of age; Well balanced and aesthetically pleasing facial profile; Class-I molar and canine relation, normal overjet and overbite with midline coinciding; No history of orthodontic, orthognathic or plastic surgery treatment.

Exclusion Criteria: Patients below 18 years of age; Patients having Class II and Class III Profile; Patients having previous history of Orthodontic or Orthognathic treatment; Patients having asymmetry of face; Patients not willing to give consent for study.

Implementing the Survey: The survey was systematically scheduled to spread over a period of 6 months from August 2017 to August 2018. The team, with a postgraduate students and a intern screened the patient reporting the OPD. Written Informed consent was obtained from the study subjects before examination. The examination of the subjects were examined seated on the dental chair. The examination was done with the single examiner so as to remove the inter examiner variability. The present analysis was made on lateral cephalograms. The base line used for comparison of most of the data in this analysis is a constructed plane called as Horizontal Plane (HP). It is constructed by drawing a line 7° from SN, intersecting at N point. The reference plane used in the study was arbitrary and was constructed assuming SN plane is normal (Figure 1).

From the digitized points, six angular and 17 linear measurements were obtained and divided into 5 Groups. Cranial base (Figure 2):

1. Posterior cranial base (AR-PTM) mm: a distance from AR to PTM, parallel to HP.
2. Anterior cranial base (PTM-N) mm: a distance from PTM to N, parallel to HP.

Horizontal skeletal relationship (Figure 2):

1. Facial convexity (N-A-PG): an angle formed by the line N-A and the line A-pG.
2. Maxillary protrusion (N-A) mm: a distance from point A to perpendicular line from N, parallel to HP.
3. Mandibular protrusion (N-B) mm: a distance from point B to perpendicular line from N, parallel to HP.

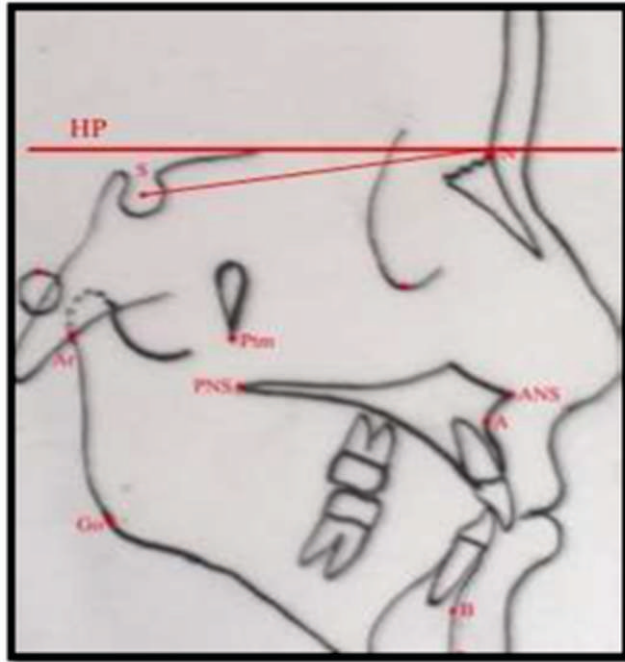
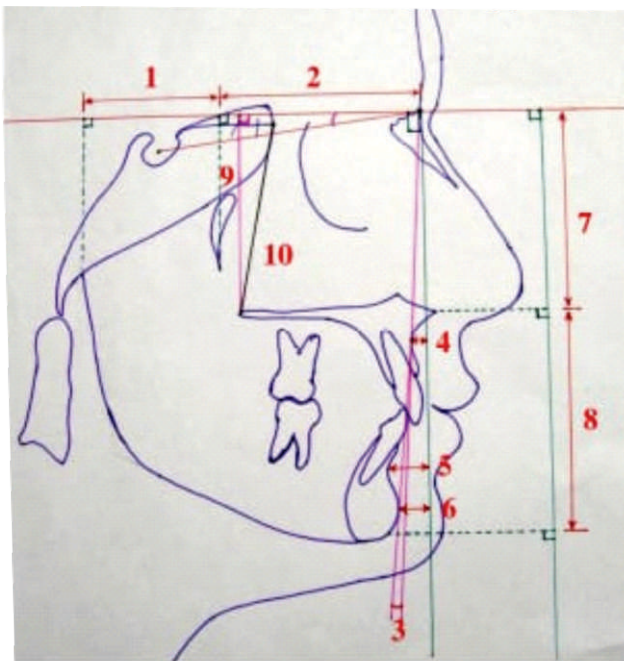
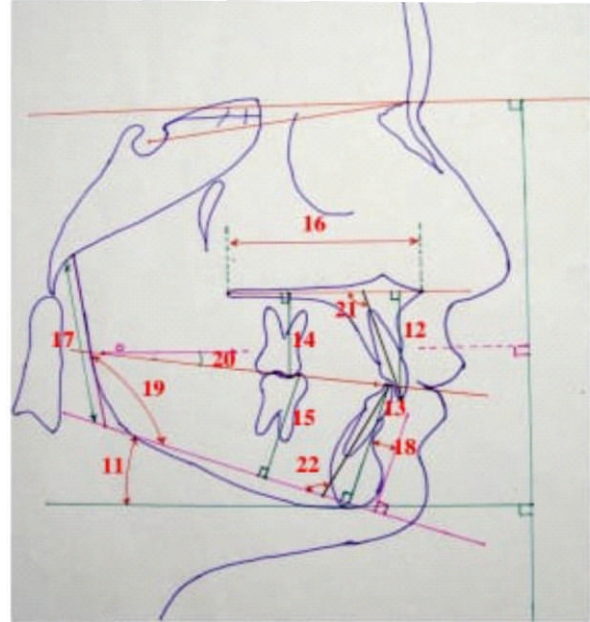


Figure 1: Cephalometric Diagram showing HP Plane.



- | | |
|-------------------------------|-----------------------------|
| 1. Ar – Ptm (\parallel HP) | 6. N – Pg (\parallel HP) |
| 2. Ptm – N (\parallel HP) | 7. N – ANS (\perp HP) |
| 3. N – A – Pg (angle) | 8. ANS – Gn (\perp HP) |
| 4. N – A (\parallel HP) | 9. PNS – N (\perp HP) |

Figure 2: Hard Tissue Cephalometric Analysis.



- | | |
|---------------------------------|------------------------------|
| 11. MP – HP (angle) | 17. Ar – Go (linear) |
| 12. U1 – NF (\perp NF) | 18. B – Pg (\parallel MP) |
| 13. L1 – MP (\perp MP) | 19. Ar – Go – Gn (angle) |
| 14. U6 – NF (\perp NF) | 20. OP – HP (angle) |
| 15. L6 – MP (\perp MP) | 21. U1 – NF (angle) |
| 16. PNS – ANS (\parallel HP) | 22. L1 – MP (angle) |

Figure 3: Hard Tissue Cephalometric Analysis.

- Chin protrusion (N-PG) mm: a distance from pogonion to a perpendicular line from N, parallel to HP.

Vertical skeletal relationship (Figure 2 & Figure 3):

- Upper anterior facial height (N-ANS) mm: a distance from N to ANS, perpendicular to HP.
- Lower anterior facial height (ANS-GN) mm: a distance from ANS to GN, perpendicular to HP.
- Upper posterior facial height (PNS-N) mm: a perpendicular distance from HP to PNS.
- Mandibular plane angle (MP-HP): an angle formed between GO-GN line and HP.

Vertical dental relationship (Figure 3) :

- Upper anterior dental height (U1-NF) mm: a perpendicular line from the incisal edge of upper incisor to NF.
- Lower anterior dental height (L1-MP) mm: a perpendicular line from the incisal edge of lower incisor to MP.
- Upper posterior dental height (UMT-NF) mm: a perpendicular line from the mesiobuccal cusp tip of upper first molar to NF.
- Lower posterior dental height (LMT-MP) mm: a

Table 1: Comparison of COGS Analysis on the basis of gender using Burststone Analysis

Measurements	BURSTONE ANALYSIS			
	Female	Male	t value	p value
Cranial Base				
Ar – Ptm (mm)	35.90 ± 3.1	38.56 ± 3.4	2.06	0.02*
Ptm – N(mm)	51.74 ± 4.8	55.74 ± 5.9	2.11	0.03*
Horizontal (Skeletal)				
N-A-Pg (Deg)	5.12 ± 5.3	5.40 ± 6.25	0.65	0.59
N-A(mm)	2.58 ± 3.28	0.98 ± 1.38	3.06	0.01*
N-B(mm)	-1.40 ± 2.82	-3.00 ± 3.2	9.68	0.01*
N-Pg (mm)	-2.4 ± 4.84	0.81 ± 2.7	4.39	0.01*
Vertical (skeletal)				
N-ANS(mm)	52.6 ± 3.09	54.8 ± 3.6	1.42	0.11
ANS-GN(mm)	64.46 ± 4.82	69.56 ± 4.3	2.38	0.03*
PNS-N(mm)	47.67 ± 1.70	55.79 ± 3.4	15.34	0.01*
MP-HP (Deg)	25.02 ± 6.45	20.46 ± 6.2	5.58	0.01*
Vertical (Dental)				
U1-NF(mm)	28.41 ± 3.08	30.81 ± 2.6	1.99	0.04*
U6-NF(mm)	23.84 ± 2.58	25.55 ± 2.9	2.49	0.03*
L1-MP(mm)	39.94 ± 5.93	44.23 ± 3.7	4.23	0.01*
L6-MP(mm)	32.37 ± 2.64	36.51 ± 2.9	3.19	0.01*
Maxilla and Mandible				
PNS – ANS(mm)	52.47 ± 3.40	54.25 ± 2.8	1.59	0.12
Ar-Go (mm)	45.80 ± 4.39	53.19 ± 4.9	6.09	0.01*
Go-Pg (mm)	74.85 ± 5.04	82.75 ± 5.4	4.58	0.01*
B-Pg (mm)	5.84 ± 1.85	8.75 ± 1.9	12.29	0.01*
Ar-Go-Gn (Deg)	122.10 ± 4.84	122.45 ± 7.9	0.21	0.90
Dental				
OP-HP (Deg)	6.85 ± 5.10	9.45 ± 5.9	4.85	0.01*
A-B(mm)	3.67 ± 2.79	2.58 ± 3.5	2.74	0.03*
U1-NF (Deg)	113.12 ± 5.99	115.82 ± 4.9	1.94	0.07
L1-MP (Deg)	99.86 ± 6.42	98.24 ± 6.3	1.25	0.29

* Significant, Student T test

perpendicular line from the mesiobuccal cusp tip of lower first molar to MP.

Maxilla and mandible (Figure 3):

1. Maxillary length (PNS–ANS) mm: a distance from PNS to ANS, parallel to HP.
2. Mandibular ramus length (AR–GO) mm: a line from AR to GO.
3. Mandibular body length (GO–PG) mm: a distance from GO to PG.
4. Chin depth (B–PG) mm: a distance from B point to a perpendicular line to MP through PG.
5. Gonial angle (AR–GO–GN): an angle between ramal length and MP.

STATISTICAL ANALYSIS:

The data was transformed from pre-coded survey form to computer. The job of data entry, comparison of the study population was done by using student t test with the help of statistical package of social sciences (SPSS version 22.0). The level of statistical significance was set at $p \leq 0.05$.

RESULTS:

The mean Cephalometric norms that had been found in Bhopal (Central India) population using HP plane (Burststone Analysis) was divided in 5 parts. Various angular and linear measurements for both hard and soft tissues among males and females

Table 2: Comparison of norms between the study and Caucasian males.

Measurements	Male			
	Male	Standard	t value	p value
Cranial Base				
Ar – Ptm (mm)	38.56 - 3.4	37.1 - 2.8	0.45	0.09
Ptm – N(mm)	55.74 - 5.9	52.8 - 4.1	2.24	0.03*
Horizontal (Skeletal)				
N-A-Pg (Deg)	5.40 - 6.25	3.9 - 6.4	2.89	0.02*
N-A(mm)	0.98 - 1.38	0 - 3.7	1.04	0.45
N-B(mm)	-3.00 - 3.2	-5.3 - 6.7	3.59	0.01*
N-Pg (mm)	0.81 - 2.7	-4.3 - 8.5	3.69	0.01*
Vertical (skeletal)				
N-ANS(mm)	54.8 - 3.6	54 - 3.2	0.74	0.45
ANS-GN(mm)	69.56- 4.3	68.6 - 3.8	0.89	0.31
PNS-N(mm)	55.79- 3.4	53.89 - 2.9	1.69	0.11
MP-HP (Deg)	20.46- 6.2	24.0 - 5.0	2.47	0.03*
Vertical (Dental)				
U1-NF(mm)	30.81- 2.6	30.5 - 2.1	0.15	0.85
U6-NF(mm)	25.55- 2.9	26.2 - 2.1	0.89	0.27
L1-MP(mm)	44.23 - 3.7	45.0 - 2.1	0.55	0.66
L6-MP(mm)	36.51 -2.9	35.8 - 2.6	1.14	0.17
Maxilla and Mandible				
PNS – ANS(mm)	54.25 - 2.8	57.5 - 2.5	1.59	0.12
Ar-Go (mm)	53.19- 4.9	52.0 - 4.2	6.09	0.01*
Go-Pg (mm)	82.75 - 5.4	83.7- 4.6	4.58	0.01*
B-Pg (mm)	8.75- 1.9	8.9 - 1.7	12.29	0.01*
Ar-Go-Gn(Deg)	122.45- 7.9	119.0 - 6.85	0.21	0.90
Dental				
OP-HP (Deg)	9.45- 5.9	6.1 - 5.1	4.85	0.01*
A-B(mm)	2.58- 3.5	-1.1- 2.0	3.74	0.01*
U1-NF(Deg)	115.82- 4.9	111 - 4.7	2.65	0.03*
L1-MP(Deg)	98.24- 6.3	95.9 - 5.7	2.89	0.03*

* Significant, Student T test

are tabulated. All readings obtained were subjected to statistical analysis for calculating mean and standard deviation (SD).

The standard values between males and females were compared with the help of student t test. The values show significant differences between

males and females in most of the parameters (Table 1).

The values are compared with Caucasian population by using unpaired t test. The Cephalometric norms for males show significant difference between study population and Caucasian population (Table 2). The Cephalometric norms for females also show significant difference between

Table 3: Comparison of norms between the study and Caucasian Females.

Measurements	Female			
	Female	Standard	t value	p value
Cranial Base				
Ar – Ptm (mm)	35.90 ± 3.1	32.8 ± 1.9	2.15	0.04*
Ptm – N(mm)	51.74 ± 4.8	50.9 ± 3.0	2.24	0.03*
Horizontal (Skeletal)				
N-A-Pg (Deg)	5.12 ± 5.3	2.6 ± 5.1	2.89	0.02*
N-A(mm)	2.58 ± 3.28	-2 ± 3.7	1.04	0.45
N-B(mm)	-1.40 ± 2.82	-6.9 ± 4.3	3.59	0.01*
N-Pg (mm)	-2.4 ± 4.84	-6.5 ± 5.1	3.69	0.01*
Vertical (skeletal)				
N-ANS(mm)	52.6 ± 3.09	54 ± 3.2	0.74	0.45
ANS-GN(mm)	64.46 ± 4.82	61.3 ± 3.3	0.89	0.31
PNS-N(mm)	47.67 ± 1.70	50.6 ± 2.2	1.69	0.11
MP-HP (Deg)	25.02 ± 6.45	23.0 ± 5.0	2.47	0.03*
Vertical (Dental)				
U1-NF(mm)	28.41 ± 3.08	27.5 ± 1.7	0.15	0.85
U6-NF(mm)	23.84 ± 2.58	23.0 ± 1.3	0.89	0.27
L1-MP(mm)	39.94 ± 5.93	40.8 ± 1.8	0.55	0.66
L6-MP(mm)	32.37 ± 2.64	32.0 ± 1.9	1.14	0.17
Maxilla and Mandible				
PNS – ANS(mm)	52.47 ± 3.40	52.6 ± 3.5	1.59	0.12
Ar-Go (mm)	45.80 ± 4.39	46.8 ± 2.5	6.09	0.01*
Go-Pg (mm)	74.85 ± 5.04	74.3 ± 5.8	4.58	0.01*
B-Pg (mm)	5.84 ± 1.85	7.2 ± 1.9	12.29	0.01*
Ar-Go-Gn (Deg)	122.10 ± 4.84	122.0 ± 6.9	0.21	0.90
Dental				
OP-HP (Deg)	6.85 ± 5.10	7.1 ± 2.5	4.85	0.01*
A-B(mm)	3.67 ± 2.79	-0.4 ± 2.5	3.74	0.01*
U1-NF(Deg)	113.12 ± 5.99	112 ± 5.3	2.65	0.03*
L1-MP(Deg)	99.86 ± 6.42	95.9 ± 5.7	2.89	0.03*

* Significant, Student t test

study population and Caucasian population (Table 3).

DISCUSSION:

The attainment of facial proportionality is one of the principal goals in the treatment of dentofacial deformities and can be achieved with properly planned and executed orthognathic surgical techniques. The goal of maxillofacial surgery is to treat any jaw imbalance and the resulting incorrect bite, which could adversely affect the cosmetic (esthetic) appearance as well as the proper functioning of the teeth.

Most of the cephalometric analyses^[10,11] which are used today in India have originated in White North American adults. The cephalometric norms of one

ethnic group need not necessarily apply to another ethnic group because of noticeable variation of the craniofacial morphology in different ethnic groups.

Previous studies have established specific cephalometric norms with different ethnic backgrounds, showing different facial features^[10-13].

The racial, facial, and skeletal characteristics of the patient play a critical role in orthognathic surgery planning. Therefore, existence of such database becomes an absolute necessity for carrying out these surgical procedures.

Over the centuries, India has received large groups of people of different ethnical and cultural origins. This has led to dispersion of different ethnic groups in the Indian population. People living in North

India have different facial form than people living in South India.

This study was done for the purpose of establishing the cephalometric norms for population of Central India population and also to establish the individual cephalometric norms of males and females. It focused on 200 males and 200 females of Madhya Pradesh origin having a class I occlusion and well-balanced faces. The young adults were examined with age range of 18–25 years.

The COGS analysis revealed that males had increased anterior cranial base length and females had increased middle and lower third facial height, anterior divergence of mandible, in both the analysis which is in agreement to the study conducted by Trivedi K et al^[10] on Rajasthan, Mohode et al on Marathi population but contrast to the study done by Grewal et al^[12] on Indo-Aryans who have vertically growing mandible.

The study had found the significant differences among the most of the parameters as compared to the different Indian population used for comparison i.e. East Indian population by Sahoo N et al^[14], Rajasthan Population by Trivedi et al^[10], Karnatka Population by Arunkumar K. V. et al^[15], North Indian Population by Tikku T et al^[16] which shows the significant difference in facial form among the Indian population.

CONCLUSION:

Cephalometric norms were established by using HP Plane for the patient who requires maxillofacial surgery was developed by to use landmarks and measurements that can be altered by common surgical procedures.

The cephalometric norms obtained from the study were significantly different from the measurement of the Caucasian population done by Burstone and the studies conducted on different population. Therefore, it can be used with confidence for COGS Analysis in patients requiring surgical management among Central Indian Population.

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Evaluation and Comparison of Retention in Mandibular Implant Supported Overdenture by Using Ball and Flat Attachment –an in Vitro Study

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ABSTRACT

The aim of this in vitro study was to compare the retention in mandibular implant supported overdenture by using ball and flat attachments. Edentulous mandibular models were made with heat-cured polymethyl methacrylate resin. Two implant replicas (CMI), of 3.75 mm diameter and 10 mm length, were placed in the intraforaminal region. Acrylic resin mandibular overdentures were fabricated and provision was made to receive two different overdenture attachment systems: prefabricated ball/o-ring attachment (Lifecare Biosystems, Thane, India) and Hader bar and clip attachment (Sterngold, Attleboro, MA). Using a universal testing machine. Statistical analysis comprised Shapiro-Wilk test, and student t test. The statistical model revealed a significantly different behavior of the attachment systems both before and between the ball/o-ring and bar attachments developed higher retentive force as compared to the locator attachment. The bar and clip attachment exhibited the highest peak as well as the highest mean retention force at the end of the study. The Locator® attachment showed a decrease in retentive potential after an early peak. The bar and clip attachment exhibited the greater mean retention force in comparison to ball/o-ring attachment.

KEY WORDS: dental implant, overdenture, ball attachment, flat attachment

INTRODUCTION:

The most common problem associated with the management of edentulous patients is the severely resorbed mandibular ridge, especially in older age when adaptive capacities are reduced^[1-3]. This compromised situation consequently results in the fabrication of unsatisfactory dentures with poor retention and stability which can further precipitate psychosocial problems^[4-5].

The stabilization of the lower denture with two interforaminal implants has provided reliable and predictable treatment outcomes. It is regarded as the minimum standard of care for edentulous patients^[6]. Implant-supported overdentures have been shown to provide a successful long-term outcome, particularly

when used to restore edentulous mandibles. It is stated that treatment effects in conjunction with a high implant success rate, improve in oral function and patient satisfaction. Various attachment types have been employed, usually ball attachment and flat attachment. Incorporating these attachments in a denture is less time consuming and low costs of components make their use cheaper when compared to bar-clip attachment.

The Branemark system have been established for implant prostheses in the edentulous mandible: (1) implant – supported fixed prosthesis, (2) removable implant –supported overdenture and (3) combined implant –retained /soft tissue –supported overdenture prosthesis^[7].

The prognosis of the prosthesis depends on Retention. It is the function of and is directly related to the attachment system employed. The success of implant-retained overdentures primarily depends on the retentive capacity of its attachment element to sustain its long-term functionality^[8].

It is hypothesized that attachments, which provide more retention against vertical and horizontal dislodgement, will be more favourable to oral function, patient satisfaction and could be the choice

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of attachment type. To investigate this hypothesis, a study has been designed in which two attachment types are compared with respect to aspects of oral function. The purpose of this study is to evaluate and compare the retention in mandibular implant supported overdenture by using two different attachment systems.

The aim of study was to compare the retention in mandibular implant supported overdenture by using ball and flat attachments.

MATERIALS & METHODS:

The present study is an in vitro cross sectional study. The study was conducted in the Department of Prosthodontics of RKDF Dental College and Research Centre. The research had been approved by Institutional Ethical Committee of College.

Mandibular Overdentures were fabricated in a conventional manner using heat polymerized polymethyl methacrylate resin-(DPI Heat Cure, DPI, Mumbai, Maharashtra, India)

The implant analogs (CMI 3.75 mm × 10 mm) were placed in the acrylic models using physiodispenser, simulating the conventional placement of implant in osteotomy site in the mandible and subsequently secured with resin cement (Relyx™, 3M ESPE, USA). Two overdenture models were prepared and eight denture samples were prepared for each group. The samples were divided in two groups based on the attachment:

Group A: Ball/o-ring attachment;

Group B: Bar and clip attachment.

Prefabricated ball attachment (Lifecare Bio-systems, Thane, India): A metallic housing with a rubber o-ring component was used for the ball and ring attachment. Hader bar and clip attachment (Figure 1)

A castable Hader bar of length = 22 mm; diameter = 1.8 mm = 13 gauge.

Nylon rider-length = 5 mm; width = 2.6 mm - moderate Retention

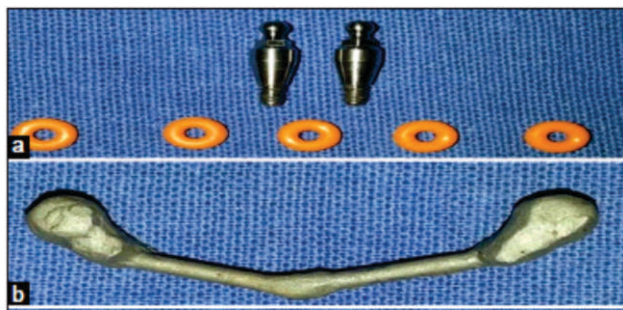


Figure 1: Showing hader bar and clip attachment.

Each attachment system was secured into the implant replicas on the acrylic resin model and the overdentures with the corresponding housing were subsequently placed on it and tightened to 35 Ncm.

Prosthetic phase:

After healing of soft tissue, Acrylic overdentures with respective attachment systems were placed on the acrylic edentulous mandibular models. Metallic clips were attached to the dentures and secured with clear autopolymerized acrylic resin (DPI Cold Cure, Clear, DPI, Mumbai, Maharashtra, India). The edentulous acrylic model was secured in place using a surveyor table.

Retention:

A universal testing machine (Model 5T, China Material Technological Co., Taipei, Taiwan) was applied to test retentive force for each experimental overdenture at a cross-head speed of 50 mm/min. This crosshead speed has been reported to approximate clinically relevant movement of the denture away from the edentulous ridge. A metallic chain connected the universal testing machine to the overdenture framework at the withdrawal loops. Vertical testing forces simulated anticipated overdenture removal forces. 21 Peak load-to-dislodgement and strain-at-dislodgement were recorded and calculated from stress-strain curves in order to determine the retention force and the change of distance between the matrix and the matrix of each attachment system respectively.

RESULTS:

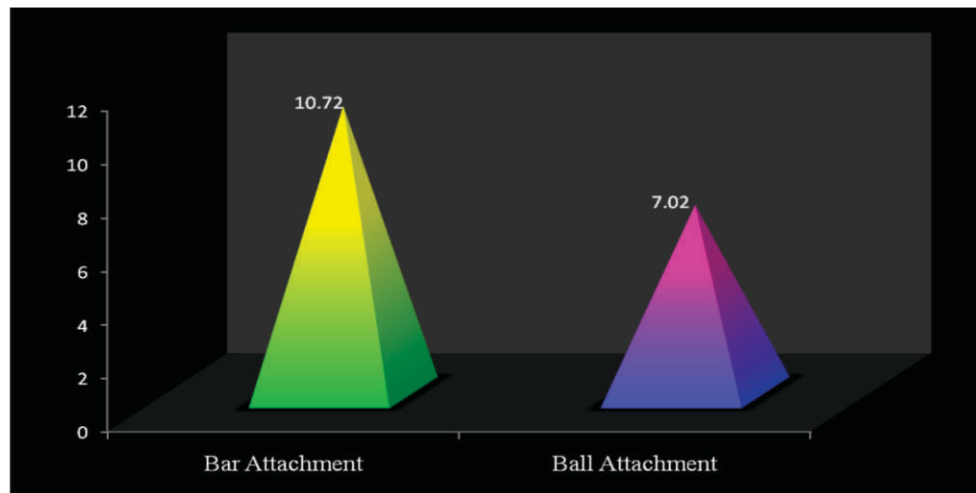
The mean force to dislodge the mandibular overdenture in all the patients was 8.87 ± 2.04 N. In bar and clip attachment group was 10.72 ± 0.76 N while in the Ball attachment group was 7.02 ± 0.70 N (Table 1; Figure 2).

The test of normality was performed on data and the Shapiro-Wilk test shows the p value of 0.53 and 0.43 which means the data is normally distributed and parametric test can be applied to the data for comparing the data (Table 2).

The t Test was used to compare the differences in force used to dislodge the denture. The mean force used to dislodge the denture was 10.72 ± 0.76 N in the bar attachment group while the force required to dislodge the mandibular denture was 7.02 ± 0.70 N in the ball attachment group. The test results show there was statistically significant difference in the amount of force required to dislodge the denture. The amount of force required in the bar attachment was greater as compared to the ball attachment. The amount of retention is more in the bar attachment group as compared to the ball attachment group (Table 3).

Table 1: Description of amount of force required to dislodge mandibular overdenture among different kind of mandibular supported overdenture.

Groups	N	Mean	Std. Deviation	Median	Range
Bar Attachment	8	10.72	.76	10.56	2.13
Ball Attachment	8	7.02	.70	7.12	1.93
Total	16	8.87	2.04	8.86	5.95

**Figure 2:** Description of amount of force required to dislodge mandibular overdenture among different kind of mandibular supported overdenture.**Table 2:** Test for Normality for the data.

Groups		Shapiro -Wilk Test		
		Statistic	df	Sig.
Force in Newton	Bar Attachment	.931	8	.528
	Ball Attachment	.920	8	.430

DISCUSSION:

The underlying principle in employing retentive implant-overdenture systems for the treatment of edentulous patients is to increase denture retention and stability, thereby promoting chewing function as well as patient comfort and compliance^[10,11].

Ball, and Bar attachments are the commonly used anchorage systems in implant-supported overdentures and their efficacy is scientifically supported^[11]. Hence, these attachment systems were chosen for this study. Splinted conventional bar attachments have demonstrated superior retentive capacities over unsplinted systems. However, they have a few disadvantages; they are initially more expensive, difficult to repair, and maintaining oral hygiene seems difficult, especially for fragile elderly individuals^[12,13].

In comparison with the bar attachments, ball anchors were preferred by clinicians because they were less technique sensitive, cost-effective, easy to use and to repair^[14].

Table 3: comparison in Amount of force required to dislodge mandibular overdenture

Groups	N	Mean	Std. Deviation	t value	p value
Bar Attachment	8	10.72	.76	10.12	0.01 (S)
Ball Attachment	8	7.02	.70		

This study was performed under a controlled experimental simulation to evaluate the retentive forces of three different types of anchorage systems used for implant-supported overdentures. The experimental set-up, however, may have had a few limitations. The sample size of the specimen used was relatively small, but was in accordance with previous similar experiments^[13].

It has to be kept in mind that for the current in vitro experiment, only mono-directional forces were applied, which does not represent a realistic model for a clinical situation with overdentures. There, the main forces are generated in the region of the first molars which will lead to rotational forces on the attachments through leverage.

During the course of the study, the different attachments showed a complex evolution with peaks as well as increasing and/or decreasing mean retentive forces. The statistical model revealed a significantly different behavior of the attachment systems.

The bar and clip attachment exhibited the significantly higher mean retention force in comparison to ball attachment at the end of the study. The same result was obtained by Shastry T et al^[17] who find The bar and clip attachment exhibited the highest mean retention force in comparison to locator and ball attachment system but found any significant difference between groups.

CONCLUSION:

The bar and clip attachment exhibited the greater mean retention force in comparison to ball/-o ring attachment. The study recommended further in-vivo research to understand the loss in retention force of various overdenture attachment systems.

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Evaluation of Surface Roughness and Tensile Strength of Ni-Cr Alloys Used for Fixed Partial Prosthesis on Recasting (Recycling)- An in-Vitro Study

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ABSTRACT

Casting is one of the primary techniques for producing shaped metals and alloys. Investigators had been making effort to recast the alloy up to many generations. The aim of present study was evaluation of surface roughness and tensile strength of Ni-Cr alloys used for Fixed Partial Denture on recasting. The alloys are divided into four groups: Group A- Pure Alloys 100%, Group B-75% New + 25% Once recast alloy, Group C-50% New +50% Once recast alloy and Group D-100% Once Recast alloy. Identical test specimens were prepared with the use of metal mold. The entire specimens were tested first for the surface roughness test by surface roughness tester and later for tensile strength test by UTM machine. ANOVA test (Analysis of Variance) was used for analyzing the result. Tensile strength of new alloy showed no statistically significant difference (p -value >0.05) from recast alloy whereas new alloy had statistically significant surface roughness (Maximum & Average surface roughness) difference (p -value <0.01) as compared to recast alloy. It is concluded that the tensile strength will not be affected by recasting of nickel-chromium alloy whereas surface roughness increases markedly.

KEY WORDS: tensile strength, recasting, surface roughness

INTRODUCTION:

Dental casting alloys play a prominent role in treatment of the dental diseases. This role has changed significantly in recent years with the improvement of all-ceramic restorations and the development of more durable resin-based composites. Though, alloys keep on being utilized as the primary material for fixed restorations and will probably be the main material for a considerable length of time to come. No other material has the combination of strength, modulus, wear resistance, and biologic compatibility that a material must have to survive long term in the mouth as a fixed prosthesis. Casting alloys have to survive long term in the mouth and also have the combination of structure, molecules, wear, resistance and biologic compatibility^[1].

The escalating cost of gold has contributed to

the widespread use of base metal alloys for fabrication of removable partial denture frameworks. In 1930's base metal alloys were introduced to dentistry by R. W. Eardle and C. H. Prange. The popularity of base metal alloys in comparison to other alloys is further enhanced by their resistance to corrosion, reduced weight, less cost and generally more favorable physical properties than those of gold^[2].

The structures and kinds of casting alloys available to the dental practitioner have changed enormously during the previous five decades. Casting alloys are categorized by several methods. According to ADA system, casting alloys are divided into three groups on the basis of wt% composition^[3].

High-noble alloys:

High-noble dental casting alloys can be divided arbitrarily into those based on gold-platinum (Au-Pt), gold-palladium (Au-Pd), or gold copper-silver (Au-Cu-Ag).

Noble alloys:

Noble alloys are much more compositionally diverse than high-noble alloys because they include gold-based alloys and other elements such as palladium or silver. These alloys have decreased gold

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content and compensate for the reduced gold by increasing copper, silver or palladium.

Predominantly base-metal alloys:

The base-metal alloys can be arbitrarily includes Ni-Cr-Be, Ni-Cr, Ni-high-Cr, and Co-Cr.

However, today's practitioner may select from alloys based on palladium, silver, nickel, cobalt, and titanium, among others.⁴ Although uses for pure metals such as gold foil and platinum foil exist in dentistry, the main role for metals in dentistry has been in alloys. Alloys are used for fixed prostheses rather than pure metals because pure metals do not have the appropriate physical properties to function in these types of restorations^[5].

In our current economy it is obligatory that dentists and technicians be cost conscious about the materials they use for fixed prosthesis. Therefore, it will be of great advantage, both economically and environmentally to recycle or to recast the alloy again and again with or without adding new alloy.^[6]

As casting procedures require more metal to be fused than is needed to fill the mold. The surplus, known as a button, is separated from the casting. The button consists of the excess molten metal which is needed to compensate casting shrinkage. The button may be reused to produce an acceptable casting and is a matter of economical consideration^[7].

As an economy measure, excess gold (buttons and sprues) has routinely been recast in combination with new metal to produce clinically acceptable castings. Gold alloys may be successfully recycled; whereas limited information is available regarding recasting of base metal alloys. Repeated casting show more stability in noble and nickel-based alloys in comparison with high noble alloys and titanium.⁸ Earlier recasting of base metal alloys was not common. Since 1980's studies have reported reuse of cobalt-chromium alloy in the recasting procedure^[9].

Due to nobility of the gold alloys, it is possible to recast the materials again and again without losing its required properties, but it's not the same for base metal alloys. There is limited information available in dental literature regarding the recasting of base metal alloys. There are no studies undertaken to check the surface roughness of recast alloys as is evident in the literature. Hence this study was carried out to find out the surface roughness & tensile strength of new alloy and recast alloys.

MATERIALS & METHODS:

This study was carried out in department of Prosthodontics, RKDF dental college and Research

center, Bhopal to verify the change in mechanical properties obtained from recasting of base metal alloys. Approval from Institutional Ethical Committee of RKDF Dental College and Research Center was taken before starting the study. The study design was cross sectional in vitro study.

The study involved testing the surface roughness and tensile strength of the new alloy and recast alloy. The study required multiple identical cast alloy specimen. The specimen had to be identical in all respect of dimension and surface finish so as to standardize them and to prevent any variability in the results.

The study included only those specimens in the study with dimension $30 \times 5 \times 7 \pm 1$ mm. The specimen with Discrepancy of >1 mm and with casting defects were excluded from the study.

The study will consist of 120 samples divided into 4 groups equally are given below: a) Group A- Pure Alloys 100%; b) Group B- 75% New + 25% Old alloy; c) Group C- 50% New + 50% old alloy and d) Group D- 100% Once Recast alloy.

PROCEDURE:

Wax patterns of desired dimension were made from metal mold according to the ADA (American Dental Association) Specification No.38 for testing of alloys used for metal / metal-ceramic restoration. Blue inlay wax was used. For standardization of the specimen Petroleum gel was applied on the glass slab and the metal mold was first positioned onto the glass slab, ensuring that the two surfaces contact each other uniformly. This would show the smooth and even surface of the wax pattern. Then molten wax is poured into mold space gently. Care was taken to avoid entrapment of air bubble. After the wax cooled, the wax pattern was removed carefully. If any distortion in the wax pattern was seen, it was discarded & a new pattern was fabricated. The surface in contact with the glass slab was used for the surface roughness test and hence all the test specimens were standardized. A direct technique of spruing was used.

A metal casting ring was taken and lined with one strip of asbestos—free cellulose acetate ring liner (BEGO). The ring liner strips were kept 3 mm short on either end of the casting ring.

The sprued wax patterns were then fixed onto the silicone crucible former (UNIDENT) and the wax pattern was then sprayed with surface tension reducing agent (DFS- SILIKON). A carbon-free phosphate-bonded investment (DEGUDENT IMPACT) was used. The necessary amount of investment material was cautiously weighed out. The investment was then

thoroughly mixed in a vacuum mixing unit (WHIPMIX) for 30 seconds as suggested by the manufacturer. After 45 minutes the casting ring was placed in cool burnout furnace (HIHEAT- LABO-31 CONFIDENT) for 60 minutes, the highest temperature programmed was 950°C. The ring was allowed to stand for another 10 min. to ensure complete wax burn out. After burnout the casting ring was carefully placed in casting machine and casting was done as per manufactures' instructions

The casting ring was allowed to bench cool to room temperature and then the casting was divested from the refractory. The sprues were detached using high speed cut-off discs and any adherent investment removed by sand blasting.

For standardization of specimens the castings were cleaned with 250 micron alumina particle (BEGO). Each Specimen was sand blasted for 5 min from distance of 50 mm. in the sandblaster.

The samples were first subjected for surface roughness test and later for tensile strength test. This order was followed as the test specimen became distorted once they are subjected for tensile strength test.

Testing the samples for Surface Roughness:

The test samples were subjected to Surface Roughness measuring tester. The samples were mounted on the tester. The diamond point stylus runs back and forth onto the samples and readings of the maximum surface roughness (maximum departure from perfection over a prescribed length) and average roughness (average departure of the surface from perfection over a prescribed sampling length) is displayed on the screen (Figure 1).

The diamond stylus on the surface roughness tester runs across a preset distance and the reading were recorded by a digital meter in terms of Rmax (maximum surface roughness), Ra (average surface roughness),

Testing the samples for Tensile Strength:

The test samples were subjected to a universal testing machine, using a specially fabricated test jig. The samples were supported across two points. Loading was done at a cross-head speed of 0.5 mm/min and the applied load recorded at a chart speed of 20 mm/min. The samples were stretched apart. Loading was continuous until a sudden decrease in the applied load was recorded. This decrease in the load values corresponded to the fracture of the samples. The reading at this particular point was noted down for each

test specimen (Figure 2).

SPSS version 22 (statistical package for social sciences) software was used for Statistical analysis. Mean and standard deviation for surface roughness and tensile strength in each group was calculated. One way ANOVA (analysis of variance) followed by Post hoc tukey test was applied for calculating significant differences among 4 groups. P values lower than 0.05 were considered statistically significant in the analysis of the results.

RESULTS:

The mean values and Standard deviation for Maximum Surface Roughness among the four groups was given in (Table 1). The comparison of maximum surface roughness of new alloy showed highly statistically significant difference from recast alloy with F value = 198.43 and p value = 0.001. The Post Hoc Tuckey test shows minimum surface roughness in Group A (Pure alloy) and minimum in Group D (100% Once Recast alloy) with significant difference between groups.

The mean values and Standard deviation for Average Surface Roughness among the four groups was given in (Table 2). The comparison of maximum surface roughness of new alloy showed statistically significant difference from recast alloy with F value = 26.54 and p value = 0.03. The Post Hoc Tuckey test shows minimum surface roughness in Group A (Pure alloy) and minimum in Group D (100% Once Recast alloy) with significant difference between group A with all the alloys.

The comparison of mean values and Standard deviations of Tensile Strength for different groups were shown in (Table 3). The study result found that tensile strength of new alloy showed no statistically significant difference from recast alloy (as p value > 0.05 that is 0.24).

DISCUSSION:

Base metal alloys currently account for a maximum portion of the fixed prosthesis alloy market. The low price of these alloys is the major attraction, although this advantage can be offset by inexperienced handling of the alloys ^[10]. Two main classes of base metal alloys are the Ni-Cr system and the Co-Cr system. This study was undertaken to evaluate the surface roughness and tensile strength of new alloy and once cast alloy. Aim of the study was to use previously used base metal alloys to produce restorations with minimum cost for the dental laboratories without



Figure 1: (A) New Alloy (B) Recast alloy (C) Mold for fabrication of test specimen (D) Wax Patterns of Specimen.



Figure 2: (A) Casting Machine (B) Cast Specimen of Alloys (C) Roughness Tester (D) Test of tensile strength.

Table 1: Comparison between new alloy and recast alloy for maximum surface roughness.

Material	N	Mean	Std. Deviation	f	p value
Group A	30	42.53	4.10	198.43	0.00 *
Group B	30	45.57	4.05		
Group C	30	47.62	4.31		
Group D	30	49.45	3.02		

(p<0.01 highly significant, p 0.01-0.05 significant, p >0.05 not significant)

Table 2: comparison between new alloy and recast alloy for average surface roughness.

Material	N	Mean	Std. Deviation	Mean Diff	f	p value
Group A	30	4.55	0.83	0.93	26.54	0.03 *
Group B	30	4.89	0.85			
Group C	30	5.03	0.85			
Group D	30	5.49	0.88			

(p<0.01 highly significant, p 0.01-0.05 significant, p >0.05 not significant)

Table 3: comparison between new alloy and recast alloy for tensile strength.

Material	N	Mean	Std. Deviation	f	p value
Group A	30	4488.40	221.64	1.43	0.24 #
Group B	30	4486.93	250.34		
Group C	30	4487.03	274.17		
Group D	30	4484.20	379.68		

(p<0.01 highly significant, p 0.01-0.05 significant, p>0.05 not significant)

compromising on the properties of the alloys. For evaluation of surface roughness, samples were mounted onto the surface roughness tester. The diamond stylus on the tester runs across a preset distance and the reading were recorded by a digital meter in terms of Rmax and Ra. Later these samples were mounted on UTM for tensile strength test.

The derived results reveal that there was non-significant difference in tensile strength between Groups. Result also shows consistent increase in maximum Surface Roughness and Average Surface Roughness with the increase in number of recasting. Hesby et al. ^[11] found no significant alteration in physical properties of alloy after 4 times recasting which is in contrast to our study which found significant increase in surface roughness of recast alloys. They also compared tensile strength first through fourth generations and found were no significant differences in tensile strength of different

generation recasting alloys.

The similar result was shown by Agrawal A et al. ^[12] in which surface roughness significantly increases with recasting but there were non significant difference in tensile strength with recasting of alloy.

James J et al. ^[13] in 2018 conducted a study divided the metals into 5 groups. Group I included samples casted with new alloy alone. Group II samples consisted of 75% new alloy and 25% once casted alloy. Group III was casted with 50% of each. Group IV with 25% new metal and 75% previous alloy and samples of Group V samples were casted with once casted alloy alone. They found slight variation in mean tensile strength which was statistically insignificant.

However the older studies by Nelson et al ^[1] in 1986 and Issac & Bhat ^[14] in 1998 showed significant decrease in Tensile strength on Recasting. Their microstructures showed large amounts of contamination, Porosity, and inclusions, which

increased with each casting generation.

Bandela V and Kanaparthi S^[15] in their review article had included 44 studies. They founded no changes in mechanical properties on recasting of alloy.

Ronald G. Presswood^[7] observed the color and the chemical composition of recast alloys & established no notable change in the composition after six melts of the alloys. So alloy was highly castable but Variations of tensile strength and surface roughness within and among groups were present. The direction and the angle of a sprue attachment may be the possible sources of variations in recorded results.

According to Anusavice^[2], the classification of causes for defective castings, one of them is surface roughness and irregularities. The outer surface of the casting necessitates additional efforts in polishing and finishing whereas on the tissue surface prevent a proper seating of casting.

Thus it can be hypothesized by this study that causes for the surface roughness is probably related to the compositional change, micro porosity, loss of certain trace elements^[7] such as manganese, chromium and molybdenum, the oxide layer formation and¹ incorporation of oxygen and nitrogen^[6].

Surface roughness, readily apparent in all castings of study and is an ever present problem. Castings that contain porosity possess a reduced effective cross-sectional area equal to the size of the defect. These essentially weakened areas affect physical characteristics and alter test results.

CONCLUSION:

Tensile strength of new alloy showed statistically non significant difference on comparison with recast alloy used in 25%, 50% and 100%. However, surface roughness increases as the percentage of recast alloy used for preparation of cast. It is minimum for new alloy, then 25% recast alloy, 50% recast alloy and maximum for 100% recast alloy.

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Evaluate the Effectiveness of Video Assisted Teaching Programme on Knowledge of Infection Control Measures among Nursing Students

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ABSTRACT

Infectious diseases are continuing threat to all patients, regardless of the age, gender, lifestyle, ethnic background and socioeconomic status. Health care is always facing new danger from incurable infections. Nurses play an important role in the health care team, they need to have current knowledge related to emerging and re-emerging infectious diseases. Students and nurses are often exposed to various infections during their clinical experience as a part of curriculum. As a member of health care team, nursing students have huge responsibility to protect themselves, patients and other members of health team.

The aim of the study was to impart the knowledge on infection control measures through video assisted programme among nursing students in order to protect themselves and patients in the clinical field. A quasi-experimental study, one group pre- and posttest design, 150 nursing students was conducted in selected nursing college. Pretest was assessed with demographic profile of nursing students and knowledge questionnaire followed by videos was displayed to the participants regarding specific infection control measures of Hand hygiene and personal protective equipment's (PPE). The post test was conducted after 7 days with same tools used in pretest assessment. The level of knowledge on hand washing technique after video assisted teaching programme on infection control measures increased significantly by 50% in the posttest with mean difference of 2.18, $t=14.76$; the level of knowledge on PPE after video assisted teaching programme on infection control measures increased significantly by 57.4% in the posttest with mean difference of 1.02, $t=14.42$ at 0.05 level of significant. Statistically significant association between the pretest level of knowledge on hand washing with scores of nursing programme ($\chi^2=39.76$, $p<0.001$), year of experience ($\chi^2=33.19$, $p<0.001$), year of study ($\chi^2=41.35$, $p<0.001$); association between the pretest level of knowledge on PPE with scores of gender ($\chi^2=15.50$, $p<0.001$) nursing programme ($\chi^2=54.07$, $p<0.001$), year of experience ($\chi^2=41.65$, $p<0.001$), year of study ($\chi^2=70.46$, $p<0.001$) was found. Video-assisted teaching programme was effective to enhance the knowledge of hand washing and use of PPE as infection prevention control measures among nursing students in order to protect themselves and patients their practice field and community.

KEY WORDS: hand washing, infection control, knowledge, video assisted teaching programme, personal protective equipment

INTRODUCTION:

Infectious diseases are great threat to all members of health care team and patients regardless of the age, gender, lifestyle, ethnic background and socioeconomic status. They cause suffering, death and impose a financial burden

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on the society. The history of infection control practices commence to take place in hospitals in 1840 when the importance and influence of hand washing was brought to keen attention in the medical area. Then in 1854, Florence Nightingale was pioneer to document the importance of hygienic environment for good health. Her work is the first ever evidence highlighting the relation of good health to hygienic environmental factors (air, water, light, efficient drainage and cleanliness). Infection control is one of the most important aspects of contemporary hospital management^[1].

The World Health Organization (WHO) defined standard precautions as meant to reduce the

risk of transmission of blood borne and other pathogens from both recognized and unrecognized sources, they are the basic level of infection precautions which are essential in the care of all patients. Nursing has important role in the prevention of infectious diseases in the care of persons and families having infectious diseases^[2].

As per the health and safety executive guidelines (1992) on personal protective equipments (PPE), "It is defined as 'all equipment which is intended to be worn or held by a person at work and which protects him against one or more risks to his health or safety'. PPE are safety helmets, masks, gloves, eye protection, gown, and safety footwear. It is to paid attention towards the proper fitting PPE, wearing poorly fitting PPE can lead to a number of problems such as excessive sweating, friction, discomfort, also finger and hand muscle fatigue^[3].

As per Centers for Disease Control and Prevention (CDC) guidelines (1996) the following standard precautions measures replace the old universal precautions system such as (a) Hand washing: wash hands before and after touching the patients, equipments, patient surfaces, before and after any procedure and immediately whenever required to avoid the transfer of microorganisms. (b) Gloves: Clean and sterile gloves are necessary to wear when touching body fluids, blood, secretions, excretions, and contaminated items. (c) Masks, eye protection, face shields: Masks, eye protection and a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures. (d) Gowns: Clean and sterile gown to protect skin and to prevent soiling of clothing of Health care workers during procedures, exposure to splashes or sprays of blood, body fluids, secretions, or excretions. (e) Patient care equipments: the equipment gets soiled when exposed to blood, body fluids, secretions, and excretions. The equipments used to infected patients, there may be a chance of transfer of microorganisms from one patient to others or to environments. Hence, taking care of patient care equipments, process of cleaning, sterilizing and discarding procedure adopted appropriately. (f) Environmental control: The policies and guidelines of the hospital must ensure the adequate infection prevention and control procedures for the routine care, cleaning of environmental surfaces, taking care of bedside equipment, beds, bed rails, and other frequently touched surfaces, and ensure that these procedures are being followed as per the guidelines/ standard operating procedure or institutional policy^[4].

Health care is always facing new danger from

incurable infections. Nurses being important role in the health care team, they need to have adequate knowledge and skills regarding emerging and re-emerging infectious diseases. Nurses have to play multidimensional role and their skills have to be combined with a specialized knowledge and practice base to ensure improved health status of the family. Student nurses are often exposed to various infections during their clinical education, and as health care workers, nursing students have huge responsibility to protect themselves, patients and their families from challenging work environment. It is very important for the nurse educators to involve the student nurses in understanding the transmission, risk factors, causes, control and preventive aspects of infectious diseases. The aim of the study to impart the knowledge on infection control measures through video assisted programme among nurses in order to protect themselves and patients their practice field and community.

Statement of the Problem: A study to evaluate the effectiveness of Video Assisted Teaching Programme on knowledge of Infection Control Measures among nursing students. The objectives of the study were to: 1) assess the demographic profile of the nursing students; 2) assess the level of knowledge on hand washing technique before and after video assisted teaching programme on knowledge of infection control measures among nursing students; 3) assess the level of knowledge on use of personal protective measures before and after video assisted teaching programme on knowledge of infection control measures among nursing students; 4) evaluate the effectiveness of video assisted teaching programme on knowledge of infection control measures among nursing students; 5) Associate the demographic profile of the nursing students with pretest level of knowledge on hand washing among nursing students and 6) Associate the background profile of the nursing students with pretest level of knowledge on use of personal protective measures among nursing students.

MATERIALS & METHODS:

The study was aimed to evaluate the effectiveness of video assisted teaching programme on knowledge of infection control measures among nursing students in Bhopal Nursing College, BMHRC, Bhopal. A quantitative research approach and pre-experimental one group pretest and post test research design was used. The sample of 150 nursing students of GNM and Post Basic BSc nursing were the samples of this study. They were recruited through probability

random sampling techniques used in this study. Each group consists of 25 participants. The tools used for data collection were background profile questionnaire, structured questionnaire on hand washing techniques with 10 items and use of personal protective equipments (PPE) with 15 items.

The tools used in this study were validated by nursing and medical experts. Video program on infection control was developed which includes source of infection, routes of transmission, chain of infection, barriers of infection, hand washing technique and wearing - removal (donning and doffing) of PPE. It was edited and structured by members of research team and it was validated by experts. The conceptual framework used in this study was general system theory with input, process and output. The data collection was done from September 2015 to October 2015. The purpose of the study was explained to each candidate. Ethical and administrative permissions obtained from the institution. First day, the pretest data collected with demographic profile questionnaire, structured questionnaire on hand washing techniques with 10 items and use of personal protective equipments (PPE) with 15 items and the same day video assisted teaching programme implemented and after 7th day the post test was conducted with

same group by using same questionnaire. The data were analyzed by using descriptive and inferential statistics (Figure 1).

RESULTS:

Among 150 nursing students, 24(16%) students were in the age group of 19 years and majority 112(74.6%) were in the age group of 20 years and above. Majority of the participants 114(74%) were female. 130 (86%) undergone GNM course. 20 (14%) belongs to Post Basic Bsc Nursing students (First year). In regards to previous clinical experiences of nursing students, majority, 130(86%) nursing students had no clinical experience, 10(6.6%) had 1-2 years of clinical experience and 10(6.6%) had 3-5 years of clinical experience.

The above (Table 1) shows that, before video teaching program the level of knowledge on hand washing was 7.3% (11) and it was increased after the intervention 57.3%(86) ie., the level of knowledge on hand washing technique after video assisted teaching programme on infection control measures increased significantly by 50% in the posttest.

The above (Table 2) shows that before and after video assisted teaching programme on knowledge of hand washing technique, the mean score was

Table 1: Assess the knowledge on hand washing technique before and after video assisted teaching programme on infection control measures (n =150).

Hand washing technique	Inadequate knowledge		Moderate knowledge		Adequate knowledge	
	Frequency	%	Frequency	%	Frequency	%
Before video assisted teaching programme	78	52	61	40.7	11	7.3
After video assisted teaching programme	07	4.66	57	38	86	57.33

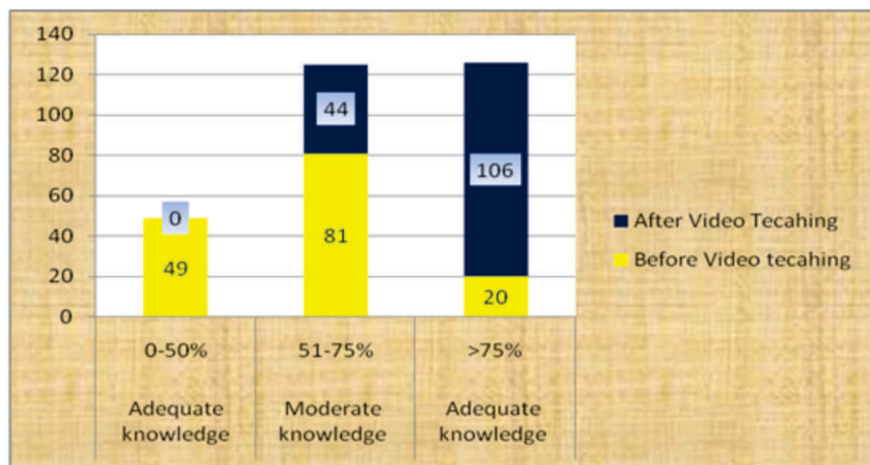


Figure 1: Assess the knowledge on use of PPE before and after video assisted teaching programme on infection control measures.

Table 2: Evaluate the effectiveness of video assisted programme on knowledge of hand washing technique (n=150).

Knowledge on Hand washing technique	Mean score	SD	Difference in mean	t-value
Before video assisted teaching programme	5.44	1.38	2.18	14.76
After video assisted teaching programme	7.62	1.158		df=149, p<0.05 level of significance *

Table 3: Evaluate the effectiveness of video assisted programme on knowledge of use of PPE (n=150).

Knowledge on Use of PPE	Mean score	SD	Difference in mean	t-value
Before video assisted teaching programme	8.86	2.48	1.02	14.42
After video assisted teaching programme	12.32	1.50		df=149, p<0.05 level of significance *

5.44, with SD 1.38; mean score was 7.62 and SD 1.158 respectively. Hence the effect of video assisted programme on knowledge of hand washing was found significant at 0.05 level with t value of 14.76. The above (Table 3) shows that, before and after video assisted teaching programme on knowledge of use of PPE, the mean score was 8.86, with SD 2.48; mean score was 12.32 and SD 1.50 respectively. Hence the effect of video assisted programme on knowledge of PPE was found significant at 0.05 level with t value of 14.42.

DISCUSSION:

Associate the background profile of the nursing students with knowledge on hand washing among nursing students. Statistically the significant association between the pretest level of knowledge on hand washing with scores of the type of nursing programme ($\chi^2=39.76$, df=1), year of experience ($\chi^2=33.19$, df=4), year of study ($\chi^2=41.35$, df=6) were significant at 0.05 level of significance and age and gender were not significant.

Associate the background profile of the nursing students with knowledge on use of personal protective measures among nursing students. Statistically the significant association between the pretest level of knowledge on PPE with scores of the Gender ($\chi^2=15.51$, df=1), the type of nursing programme ($\chi^2=54.07$, df=1), year of experience ($\chi^2=41.65$, df=4), year of study ($\chi^2=70.47$, df=6) were significant at 0.05 level.

Implications:

The findings of the study have implications in nursing education, nursing administration and nursing research. Video assisted teaching programme can be

incorporated as blended teaching methods to impart the knowledge on infection control. Emphasis on hand washing technique of nurses will reflect on the quality of care. Conduction of inservice education among nurses through video assisted demonstration of hand washing and use of PPE to prevent the infection control measures. It provides the model for teaching to impart the knowledge and can be utilized for the other procedure in the clinical areas.

Recommendations:

Demonstration vs video assisted teaching on knowledge of hand washing can be conducted. Similar studies with large sample size can be conducted to generalize the study findings. Practice of infection control measures can be measured with structured check list or standardized tool. A comparative study can be done on nurses, nursing students, paramedical staffs and students or with different health care personnel.

CONCLUSION:

A video assisted teaching programme is the effective strategy to improve the knowledge of nursing students on hand washing techniques and use of PPE to prevent the infection and control measures. It ensures the safety of the patients as well as health care personnel. As nurses are the important members of the health care team they must acquaint themselves with adequate knowledge with proper updating to protect themselves and community against infectious diseases.

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Nurses on the Frontline Against the COVID-19 Pandemic: An Experience

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BACKGROUND:

Corona virus disease 2019 (COVID-19) was first reported from Wuhan, China in late December 2019 and was declared a global pandemic by the World Health Organization (WHO) on March 11, 2020. As on November 23, 2021, the COVID-19 pandemic has infected more than 256 million individuals globally, leading to 5 million deaths and has disrupted health care systems across the world. ^[1] Nursing staff, who have always been key frontline health care workers, have been instrumental in the COVID-19 response worldwide, often at the cost of their own physical and emotional well-being.^[2,3]

The first case of COVID – 19 was reported in India on January 27, 2020, in Kerala, and the first case was diagnosed on March 9, 2020 in MP Central India. In this article, an effort is taken to describe the experience of managing team of nurses who were at the forefront against COVID-19, ably supported by others such as patient navigators, clinical research staff, and administrators.

The selected hospital is one of the hospitals in central India from private sector. Early in the pandemic, the hospital was designated as a COVID-19 hospital for all patients. There is lack of data regarding the impact of the double burden of COVID-19 and shortage of nursing staff in the face of lockdown, other manpower shortage, and personal challenges.

The hospitals began preparations to deal with the pandemic in early March 2020. Several policies were implemented in the hospital to mitigate the risk to staff, patients, and caregivers to ensure effective hospital functioning. The initial preparations included creation of a core action group to review evidence, create and update standard operating procedures (SOPs), and oversee daily operations. Nursing staff

were an integral part of this action group and expanded their services beyond routine hours. The action group communicated via a What's App group, and key members of the action group met on a daily basis to review the unfolding situation. The following areas were recognized for urgent action:

1. Screening patients and staff to identify those likely to be infected;
2. Setting up of a fever clinic and facility for testing for COVID-19 and
3. Creation of isolation wards and stepping up the infection prevention control measures.

Subcommittees of the core action group were created to look into each of these aspects. A team of medical staff constantly updated the SOPs based on evolving evidence. Subsequently, when selected hospital became a COVID-19 vaccination center in March 2021, nursing staff took on the additional responsibility of managing the vaccination center.

Screening of Patients and Staff :

One of the measures adopted since March 2020 was screening of patients and accompanying persons at hospital entry points, and thermal screening for hospital staff.

The staff deputed from various departments of the hospital like nursing, paramedical, dental and medical and administration. The identified frontline personnel were rendered intensive training on administering a COVID-19 questionnaire and use of thermal screening to identify high-risk individuals, thus segregating the COVID-19 suspects from others. Those who were identified as high risk- having history of travel, symptoms, high body temperature-were referred to a dedicated “fever clinic” for further evaluation. Others who were screened negative at the entrance were directed to access regular hospital services.

Entry access into the hospital was limited to only one person accompanying the patient, extendable to two if the patient was on a wheelchair. The frontline staff were trained to safeguard themselves from the infection. This training included appropriate use of personal protective equipment (PPE), social

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distancing, and hand hygiene.

Setting up of a Fever Clinic and Facility for Testing for COVID-19:

A section of the main part of the hospital near the entrance was converted to a 'fever clinic' where screened individuals identified as high risk could be evaluated further. Facilities for collecting swabs for reverse transcription polymerase chain reaction (RT-PCR) testing, waiting areas for those awaiting the results of the swab, and separate entrance and exit pathways to avoid contacts between suspects and other staff and patients were also set up.

Nursing staff worked in the fever OPD for sample collection, educating the patients and relatives, training other staff and carried out audits. We recognized that hospital staffs, in addition to fulfilling their professional roles, were also concerned about their own safety and that of their families.

Nursing students, having strong professional bond with the selected community, were identified as key members to play the vital role in spreading the right knowledge related to COVID-19 to community and nearby catchment area. Therefore, the process of training nursing undergraduate students and hospital staff on various aspects of COVID-19 started with the objective of educating and guiding the community in that area for reporting to nearby available health facility under Ayushman Bharat.

A group of nursing staff underwent the initial training and then acted as trainers for the other individuals. These training modules were conducted in small batches and included generating awareness about the symptoms of COVID-19, and precautions to be followed by all (respiratory and hand hygiene). In addition, they were taught about infection control practices to be followed in the wards and critical care areas such as appropriate use of PPE, measures to be followed while caring for those with COVID-19, and management of waste disposal.

Periodic audits were performed to assess retention of information and need for retraining.

A separate facility near the hospital was identified as an isolation facility for those with asymptomatic or mild COVID-19, who did not have facilities for home isolation. Within the hospital's existing facilities, new areas were set up by reorganizing various inpatient and outpatient areas to create segregated space for COVID-19 care. An intensive care unit (ICU) facility was created for the patients who required ventilator support and close monitoring. A separate pathway for transport of patients with COVID-19 was identified, rooms for

donning and doffing of PPE were set up, and several trial runs were performed much before we had our first patient to ensure that we were well prepared to safely manage patients with COVID-19.

Tracing of Contacts Identifying high-risk contacts of infected individuals is important to minimize the extent of transmission. Nursing staff created a group which had individuals trained in SOPs of contact tracing. The group powerfully conducted interviews of all possible contacts to identify those at high risk. The quarantine facility was set up in the hospital itself, while later on, other premises such as hotels and hostels were used as quarantine facilities. Testing/Retesting of cases and contacts Nursing staff organized by databases of those in isolation and quarantine.

Changes in Working Pattern:

Several changes were adopted to the working pattern of Nursing staff to attend to huge demand and work load in the hospital. The staff with high risk (pregnant, multiple co morbidities, and immune suppressed) were given medical leave during the peak of the pandemic. The staff from medical and surgical areas were retrained in critical care skills and deployed in ICUs. The duration of the shift was increased to 12 hours from eight hours. Monetary benefits too adopted to pay to nurses as 'Covid Allowance'.

Due to shortage of nursing staff, nursing students and faculty from nursing college too were deployed in the hospital. Due to acute shortage of nursing staff, 'Buddy concept' could not be implemented where staff is deployed to 'non covid' area, where PPE not required, in shifts alternatively. The much required 'OFF' too could not be provided to nursing staff due to acute shortage.

This led to many adjustments and physiological problems among the nursing staff. They started vocalizing their problems and difficulties faced by them. Few refused to work straight away and many started remaining absent in allotted shift. This absenteeism was managed by deploying nursing students of final years (IV and III B Sc Nursing) after convincing their parents and assuring them that their ward will be protected and will be looked after well. A transport too was arranged to pick and drop them for night shift.

It was found that most of the nurses had the responsibility to look after their family viz few had ailing old parents (15 %), few had very small babies to look after (25%)and few had to cook (45%) as home aid also was not available due to lock down, few abstain themselves due to social stigma from neighbors and

family (10%), remaining 05 % did not verbalize the reason for remaining absent. Most of the nurses who used PPE for prolonged periods reported various types of injuries.

Many a times it happened so that the nurses did not report in night shift (33%). Many a times the nursing staff on evening shift was requested to carry on with the night shift too (22%).

The role of the nursing team in dealing with the pandemic has been acknowledged by the hospital administration as one of the most essential aspects of the generally response. Nurses presented their observations and learning in hospital meetings, in National and International webinars, to allow others to benefit from their experience.

DISCUSSION:

The WHO estimates that 80,000 to 180,000 health care workers could have died with COVID-19 between January 2020 and May 2021.^[3]

Several of them are likely to have been nursing staff. Bandyopadhyay et al looked at COVID-19 infections and deaths among health care workers and found that among those infected, nurses constituted the largest proportion (38%).^[4] The impact of the pandemic on the mental health of nurses has also been well documented, with several studies reporting anxiety, depression, stress, burnout among nursing staff.^[5] A systematic review and meta-analysis looking at psychological distress among health care providers during COVID-19 in Asia establish that more than one-third of health care providers suffered from anxiety and depression, the likelihood being higher with female gender.^[6] Lack of human and physical resources and the number of colleagues infected with COVID-19 were the strongest predictors of stress, anxiety, and depression among nurses.^[7] India and found that 12 to 14% of them reported anxiety and depression among frontline nurses.^[8] Nurses have been at the receiving end of bullying and social stigma due to the perception that they are carriers of COVID-19.⁵ In a study among health care workers in India, Radhakrishnan et al found that 70% of nurses reported a stigmatizing experience during COVID-19, and that being a nurse and working in a clinical area were more likely to worsen this experience.^[9] Most of these reports are from the initial period of the pandemic where transmission was less understood and fear was high. After several months into the pandemic, and recognizing the vital role that health care workers have played, such problems and stigma do not exist anymore.

a stigmatizing experience during COVID-19, and that being a nurse and working in a clinical area were more likely to worsen this experience.^[9] Most of these reports are from the initial period of the pandemic where transmission was less understood and fear was high. After several months into the pandemic, and recognizing the vital role that health care workers have played, such problems and stigma do not exist anymore.

The use of PPE is associated with problems such as pressure, headaches, sweating, disturbances of vision, and difficulty in breathing. It has been estimated that three out of four individuals who use PPE are likely to have adverse events related to skin.^[10] Nurses, due to their long-duration shifts and fixed postings in COVID-19 wards, are more likely to experience such problems. Wearing PPE for longer than 4 hours has been identified as a significant factor for adverse events, and limiting the duration of PPE to less than 4 hours could be the solution.^[11] The training of nursing students during the pandemic has also been affected, during pandemic the classes were suspended completely and students were called for clinical duties in the hospital.

Nurses have always been a part of a multidisciplinary team and recognize the importance of teamwork through collaboration and good communication. During the pandemic, the nursing staff has taken teamwork to new heights and worked in close partnership with several other departments —patient navigation teams, administration, medical staff, clinical research staff, and many others.^[12,13]

CONCLUSION:

The WHO had designated the year 2020 as the 'year of the nurse and midwife', in the honor of the 200th birth anniversary of Florence Nightingale. It is appropriate that in this year, nurses have been the champions in the battle against COVID-19. However, in the course of this battle, nursing staff have faced several challenges which need to be addressed to ensure their continued well-being. Health Care administrations should recognize the critical role that nurses play in crisis situations and empower them while they deliver important aspects of the overall response.

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Exclusive Modified Constraint-Induced Movement Therapy for Motor Recovery in Left Hemiplegic Patient

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ABSTRACT

Chronic hemiplegics are a big challenge for the therapist to restore their motor skills and the patient survives with quality of life and dependency. The study reports a case study on the response of chronic left hemiplegic patient focusing the role of unique modified Constraint-Induced Movement Therapy as an intervention that doesn't respond to the conventional approach. The detail of how the patient progressed in the motor improvement of the paralytic upper limb is discussed. A convergent association of mCIMT & Task-oriented approach has been demonstrated as a success story for post stroke recovery in a short period of 4 weeks and in kicking off Neuroplasticity.

KEY WORDS: chronic hemiplegia, paralytic upper limb, upper extremity, post stroke, rehabilitation, physiotherapy, modified constraint induced movement therapy, conventional therapy, learned nonuse, motor recovery, case report

INTRODUCTION:

Stroke/ Cerebro-vascular Accidents is a medical emergency where there is a high mortality rate and the patient shall survive with devastating paralysis shall occur. The condition shall occur due to reduced or obstruction of blood supply to the brain. It could be ischemic, hemorrhagic, and/ or Transient Ischemic Condition. The brain deprived of oxygen and glucose through blood shall damage due to poor nutrition.

The pathology of stroke is relatively similar to the heart attack, where blood flow is disturbed due to ischemia and/ or necrosis leading to the death of peripheral tissues and so the condition is also known as Brain Attack. Mainly Stroke apart from Transient Ischemic Attacks results in enduring damage that accounts for death or severe sensory-motor deficits.

A systematic review is done by Sureshkumar Kamalakannan et al (2017) on the prevalence of Stroke in India exhibits that the incidence ranges from 105-152/ 100000 persons yearly. This value is alarming as they are very high compared to high-income countries. The review was focused on the magnitude of stroke in

the country from 2000-2008 in association to 1970-1979 studies.

Hemiplegia: Contra-lateral weakness of one side upper and lower extremities is a common post Stroke presentation. Facial muscles shall also be involved in such cases. American National Stroke Association had estimated about 90% of Stroke survivors shall have Hemiplegia. One side stroke of the brain shall lead to opposite side hemiplegia as most of the motor fibers cross to the opposite side of the cerebral cortex. Restricted movement with sensory loss shall lead to reduced activity of daily living and even dependency on others. Poor musculature shall also contribute to in-coordination, poor balance, circumduction gait, difficulty to grasp, etc. these presentations could be worse by complications like Reflux Sympathetic Syndrome, Shoulder subluxation, uncontrolled Spasticity, etc.

Rehabilitation of hemiplegic patients involves a multidisciplinary team involving a Physiotherapist, Occupational therapist, Speech therapist, Nutritionist, Vocational officer, etc. There is no substitute for therapy and effective approaches shall provide promising results. Physiotherapy is one of the prime interventions that take care of the sensory-motor recovery of the hemiplegic side. Conventional therapies like ROM exercises, Coordination & balance training, Task orientation approaches and

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Neurodevelopment techniques shall improve the voluntary control of the patient. The latest approaches are also effective in targeted groups. These advanced techniques are Functional Electrical Stimulation, Motor Imagery, Mirror Therapy, Wii Therapy, Robotics Exercises and Bio-feed Back Therapy. Assistive devices, splints and/ or a wheelchair are administrated in feebly prognostic cases.

Neuroplasticity is a phenomenon that occurs due to intense therapeutic approaches. Cortical plasticity, Brain rewiring, Neural Adaptation, etc were different terms used to describe the spontaneous alteration of the brain that takes over the functions of damaged areas and brings motor recovery or functional independence to the patient. Lots of studies are conducted to streamline the interventions and their modified protocols on enhancing Neuroplasticity in patients with Upper Motor Neuron Lesion. Though interventions stimulate, multiple mechanisms work physiologically at the brain in the process of recovery and Brain plasticity. Principles like Use it or lose it, specificity, Repetition, Intensity, Duration, Interference, Transference, etc of various interventions shall play a key role in Cortical Plasticity. Optimizing the principles of plasticity Physiotherapists can play a vital role in improving the patient's quality of life. Researches conducted on such interventions are also focused on cost-effective and early recovery competent approaches.

Chronic Hemiplegia that is more than 02 years from the onset of injury shall go to the Residual Spasticity Stage. In Upper motor neuron lesions like stroke, the muscles turn into spasticity. This shall restrict the voluntary movement and the muscles shall characterize by a velocity-dependent increase in tonic stretch reflexes. This condition gradually moves to muscle fibrosis and permanent deformity, if not rehabilitated. The development shall occur after 2 years duration. At this stage, no therapeutic interventions usually work for the patient and the chances for Neuroplasticity decline. Most of these hemiplegics suffer from upper limb impairment which shall be lifelong restraint.

Constraint-Induced Movement Therapy (CIMT) is known to the therapy community as an approach to chronic stroke patients in improving upper limb function. The technique developed by Dr. Edward Taub, a behavioral neuroscientist is studied effectively in Cerebral palsy, Brain injury and Stroke patients with hemiplegia. This technique is intended to decrease the

effect of "learned Non-use". Patients who are medically stable and in a better Neuro-muscular condition shall be benefitted from the program. CIMT works by constraining the normal side with splints/ POP and forced use of the affected upper limb for about 6 hours a day. The therapist needs to provide continuous feedback and the patient needs to be committed to the activity section. Limitations for CIMT are physiotherapists need to spare a lot of energy time and resources, whereas patients shall feel worn out with intense and prolonged exercise sections. Besides, that therapist is also worried about the patients falling in line and about some patient safety issues.

Modified Constraint-Induced Movement Therapy (m-CIMT) is subjectively developed by the therapist at their patient's convenience. A lot of efforts is done by physiotherapists recently to refine CIMT parameters and to advance it as per ease of hemiplegics. The duration and/or intensity of constraining the unaffected side and that of the paralytic arm were more on focus in m-CIMT. The clinical experts around the world are working for the refined approach as m-CIMT is cost-effective and easy to intervene even in the home environment. Focus is also on patient self-motivational interventions and psychological endorsement.

OBJECTIVE OF THE STUDY:

To highlight the outcome of the unique protocol of modified Constraint-Induced Movement Therapy (m-CIMT) in upper extremity motor recovery of a hemiplegic patient.

CASE DESCRIPTION:

The subject of this study is a 66-year-old male from Central India diagnosed with right Middle Cerebral Artery (MCA) Stroke 3 ½ years before, in 2016. The patient has then admitted to the hospital had emergency medications and preliminary Physiotherapy. As he managed to walk with partial support, he got discharged and run down from further therapy.

The subject later approached the researcher for impaired hand functions, poor balance and gait. Balance and Gait of the left hemiplegic patient were an easy goal to accomplish as these purposes are already healthier. But upper limb functions were quite compromised. After 6 weeks of continued conventional therapy, the upper extremity remained almost impaired. It was a big challenge for a physiotherapist to overcome the "Learned Non-use" of the affected limb. Moreover, Middle Cerebral Artery Stroke had severe upper limb involvement related to the lower extremity.

3½ years older neglected Stroke muscle responses shall be underprivileged. "But I have promises to keep, And miles to go before I sleep." The lines of Robert Frost remind you to take a leap ahead and to explore unheeded to keep the promise to the patient.

On examination, superficial sensations and proprioception of the affected hand were almost intact. Passive ROMs of the Wrist and Elbow were almost full. End range restrictions were there for shoulder abduction and external rotation. Muscle power arrays from 3 to 4 in various joints. He was well oriented and the higher functions were normal. Functional evaluation was done on upper limb motor serving of Fugl Meyer Assessment Scale for Stroke. Out of 66 for upper limb motor function, the patient had scored 26, from 33 items on the pre-test.

The Intervention was finalized after a detailed review of various pieces of literature and studies; **modified Constraint-Induced Movement Therapy (m-CIMT)** was confirmed. The patient had already undergone 2 months of physiotherapy and improved Balance, coordination and Gait. But upper limb functions of the hemiplegic side don't respond well. An exclusive m-CIMT program was structured for the subject with the following parameters:

- * Maximum of 1½ hours per sitting and two sections per day.
- * A long pan splint was used as the constrain material for normal hand (right side).
- * The restraint was recommended during the treatment duration and of additional 3 hours apart on busy hours.
- * Motor Relearning Program and Task-oriented approaches were used for left upper limb (non-dominant side) rehabilitation for the said therapeutic duration.
- * The participant had undergone the treatment for 6 days a week for 4 weeks.

The intervention was carried on a patient's home setup and was conducted during October-November 2019.

The patient was counseled and well-motivated for active contribution during the program. The self-divide of the subject for the given target achievement time of 4 weeks was very well commendable. Continued feedback and appreciation worked with the eagerness and hard work of the patient. Post-test with upper limb portion of Fugl Meyer Assessment scale was done on the last day of the second and fourth week. The total scores were 33 and 53 respectively for the

second and fourth week.

RESULTS:

The motor response was recorded pre and post-test by Fugl Meyer Assessment Scale (FMA). Post-test was repeated at the end of the second and fourth week for the paralytic upper limb. Heaps of positive responses were recorded for the patient at the end of the fourth week, post-intervention for the patient.

FMA for upper limb motor functions score of the subject repeated on the first day (Pre-test), end of the second week (on the course) and end of the fourth week (post-test). The scores obtained were detailed on the following chart (Table 1).

The graph of the FMA score (Figure 1) also displays a clear picture of how individual criteria responded to the intervention, m-CIMT, from day one to the end of the second and fourth week in comparison to maximum scores.

The above chart describes how the patient's condition had matured through the course of treatment. The chat displays the better prognosis in upper limb, hand and coordination categories, whereas responses were not satisfactory in wrist criteria.

Overall motor prognosis in the second week was not satisfactory, but the responses were remarkable at the end of the fourth week.

DISCUSSION:

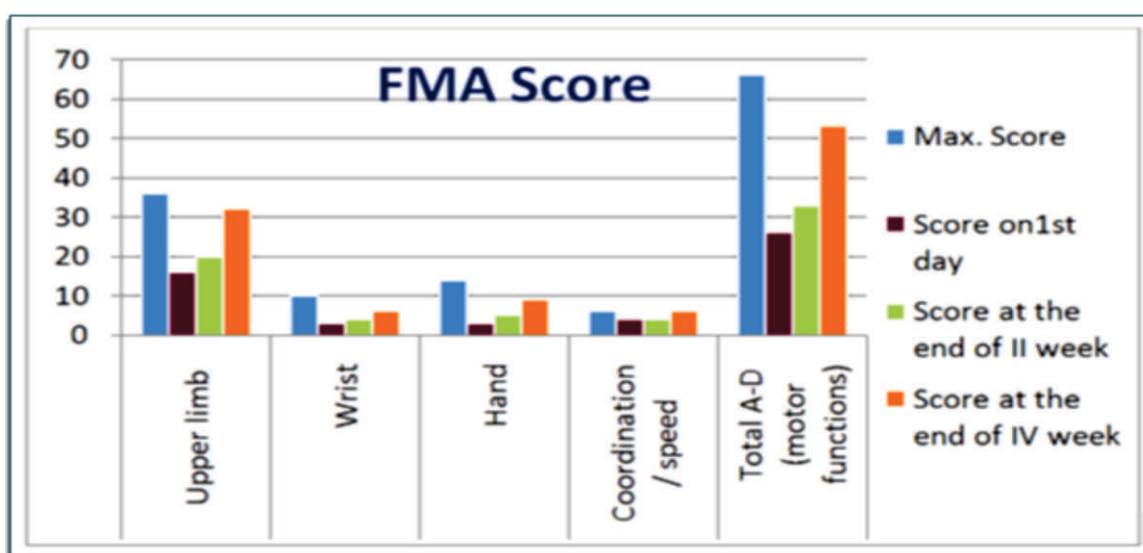
The prime intention of the study was to know whether exclusively designed modified Constraint-Induced Movement Therapy (m-CIMT) works for the hemiplegic patient. The subject's paralytic upper limb doesn't work for conventional Physiotherapy and then he was administrated with the m-CIMT.

The entire study program of the m-CIMT was done for 4 weeks, where pre-test was done before the intervention and post-test were done on the second and fourth week by Fugl Meyer assessment scale for the post-stroke patient. The total motor portion of FMA is categorized as upper limb synergy/ activity, Wrist stability, Hand functions and Coordination & speed of the upper limb. The second week's responses in all the criteria were not satisfactory, but these picked up well by the end of the fourth week. This could be due to the patient's time taken to assume the new approach and to get actively involved. Feedback and motivation in the first phase had shown a low response.

The upper limb and coordination functions improved enormously. Whereas wrist and hand functions evolutions were comparatively poor. This could be to their complexity in motor activity and time-

Table 1: The subject's scores on FMA.

Sl.No	part	Max. Score	Score on 1st day	Score at the end of II week	Score at the end of IV week
A	Upper limb	36	16	20	32
B	Wrist	10	03	04	06
C	Hand	14	03	05	09
D	Coordination/ speed	06	04	04	06
A-D	Total A -D (motor functions)	66	26	33	53

**Figure 1:** Comparison of FMA scores.

consuming more for the Neuroplasticity. Larger joints responded well with better coordination and/ or speed. The subject had initially shown some distress on wearing the pan splint for about 6 hours a day. However, he had engrossed in the tactic of the program and expressed his interest in achieving maximum motor recovery. This indicates that physical intervention with psychological endorsement was working well for the patient. During the said course no side effects were reported, though the patient complained about some discomfort during the early stage which relinquin by itself in few days.

The patient before receiving m-CIMT was undergoing conventional Physiotherapy for about 2 months, which could not break "Learned nonuse". But this long-established section would have conditioned the limb to be prepared for m-CIMT. Spasticity of the limb was in control; ROMs of upper extremity joints

were almost normal and the muscle power were 2-4 in most of the parts. All these had facilitated the speedy response when m-CIMT was applied.

The results demonstrate high significance of exclusively designed m-CIMT working for the subject. Utmost of 1½ hour per sitting twice a day is worthful. Long pan splint used as constraining material for sound hand (right side) managed the purpose successively. Motor Relearning Program and Task-oriented approaches were used for left upper limb rehabilitation were of enormous exercise. The total duration of the said program was of 4 weeks, 6 days in a week was result-oriented. In short, this unique protocol of m-CIMT is objective-directed for the patient.

The study concluded in 4 weeks and no further intervention and/ or follow-ups were done, which is a major deficiency in the conformation of the sustained effect of the approach. The single-subject – case report can't be comprehensive, but if it could shed new light on some researchers to carry forward with randomized

control trials in large groups, then this submission shall pull off its intention.

CONCLUSION:

The clinical relevance of the study is that it has highlighted chronic hemiplegic patient's considerable response to the exclusively designed m-CIMT, which overcomes the paralysis that doesn't respond to conventional therapy. The future study shall be done on a larger group, with a randomized controlled trial for the confirmation of the effect of the unique m-CIMT program. Further such studies shall also focus on m-CIMT in a sundry environment and for conditions like Cerebral palsy, Traumatic brain injury, etc with hemiplegia.

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Development and Characterization of Deflazacort Nanoparticles for the Treatment of Inflammatory Bowel Disease

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ABSTRACT

Inflammatory Bowel Disease (IBD) are difficult to control and the reappearance is the most challenging issue for the physicians. IBD includes Ulcerative colitis (UC) and Crohn's disease (CD). There are various controlled and colon targeted drug delivery systems available for the treatment with a limited success rate. Nanoparticles prepared by using the colon targeted polymers such as chitosan may improve the condition of IBD due to their smaller size, unique physicochemical properties, and targeting potential. Deflazacort is a glucocorticoid used as an anti-inflammatory, immunosuppressant and commonly prescribed drug for the patient having IBD such as Ulcerative Colitis (UC) and Crohn's Disease (CD). The purpose of the present study was to prepare and evaluate the potential of eudragit coated chitosan nanoparticles of Deflazacort for the treatment of IBD by ionic gelation method. These nanoparticles were further coated with Eudragit S-1 by the solvent evaporation technique so as to prevent drug release in the stomach and small intestine. Developed Nanoparticles were subjected to various characterization techniques such as FTIR, particle size, scanning electron microscopy (SEM), drug entrapment efficiency and zeta potential. The efficiency of drug release from prepared formulation was studied in vitro in gastrointestinal fluids of different pH. The prepared nanoparticles demonstrated the size in the nano range. The release pattern of Deflazacort from eudragit-coated chitosan nanoparticles was observed to be pH dependent. In acidic medium, the release rate was much slower however the drug was released quickly at pH 6.8 and 7.5. Subsequently, stability study at various storage temperature was also done in which the prepared formulation showed improved stability. The zeta potential of the best chitosan preparation (F2) was found to be -30.5 mV, which confirms the stability of prepared nanosuspension. Eudragit-coated chitosan nanoparticles can be a promising carrier for colon-targeted delivery of Deflazacort found to have high encapsulation efficiency and predetermined in vitro drug release profile.

KEY WORDS: Inflammatory Bowel Disease, Deflazacort, ionic gelation method, eudragit-coated

INTRODUCTION:

Deflazacort (1-(1,16)-21-(acetyloxy)-11-hydroxyl-2-methyl-5H-pregna-1,4-dieno[17,16-d]oxazole-3, 20-dione) is a synthetic glucocorticoid and an oxazoline derivative of Prednisolone. It has influential anti-inflammatory activity and immunosuppressive action^[1-2], which is quite analogous to Prednisolone. Deflazacort is a prodrug and is utilized in Duchenne muscular dystrophy (DMD), Rheumatic polymyalgia, Drug-resistant epilepsy of childhood, Idiopathic Nephrotic Syndrome (INS), renal transplant and Asthma^[3]. In India it is sold

under the trade name as Moaid, Zenflav, Defolet, DFZ, Decotaz, and DefZot. The oral route of drug administration is the most convenient and hence the preferred means of drug delivery to the systemic circulation of the body. However, oral administration of most drugs in conventional dosage forms has limitations due to their inability to restrain and localize the drug delivery system at GIT.

Because of smaller size and efficient carrier capacity, Nanotechnology is now becoming an important area of research due to its wide range of benefits in the pharmaceutical industry and applied sciences^[4,5]. Recent research reports revealed the opportunities of nanomedicine in the treatment of IBD. Nanomedicine may replace the conventional dosage forms in the treatment of IBD^[6]. Present treatment of IBD lacks cure (only remission). Nanoparticles are helpful in improving the function of current existing drugs by targeting action, solubility improvement and

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dose reduction ^[7]. Various study reports revealed the advantage of nanoformulations for IBD at minimum doses ^[8]. Chitosan nanoparticles have gained significant importance since chitosan is the natural colon targeted polymer. Because of its biocompatible properties, chitosan was gravely investigated as a potential drug carrier and is a natural linear biopolyaminosaccharide obtained by alkaline deacetylation of chitin, the second abundant polysaccharide next to cellulose ^[9]. Some studies have suggested utilizing chitosan to coat nanoparticles made of other materials to lower down their impact on the body and increase their bioavailability.

The elemental composition of the chitosan polymer is carbon (44.11%), hydrogen (6.84%) and nitrogen (7.97), because of their biocompatibility, biodegradability, low immunogenicity and low cost, chitosan has emerged as an important biomaterial and pharmaceutical excipient for drug delivery ^[10].

The formation of chitosan nanoparticles includes a simple and non toxic method known as ionic gelation method. In this method, chitosan polysaccharide is dissolved in aqueous acidic solution to get the cation of chitosan ^[11]. The solution formed is then added to the aqueous Sodium tripolyphosphate [STPP] solution under stirring conditions. In this research work, Deflazacort nanoparticles were prepared by high result oriented ionic gelation method with some slight modifications. Chitosan was utilized along with STPP. The formulations are developed with a scope of better therapeutic efficacy, solubility and penetration at the inflamed site.

MATERIALS & METHODS:

Chitosan, Eudragit S-100 was obtained from HiMedia Laboratories Ltd, Mumbai, India. STPP, acetic acid, ethanol, Span 80, acetone, dichloromethane and light liquid paraffin were purchased from Central Drug House Pvt Ltd, Mumbai, India. All other reagents and chemicals used were of analytical grade.

Preformulation Studies:

Solubility:

The Solubility of the drug was determined by weighing approximately 10 mg of drug and transferred to 7 different volumetric flask of 10 ml. Different solvents (Distilled water, 0.1 N HCl, 0.1 N NaOH, Ethanol, Methanol, pH 7.2 phosphate buffer and Chloroform) were made up to mark into the 10 ml flask respectively and shaken vigorously. The solubility was observed at room temperature.

FTIR spectroscopy:

IR spectra of physical mixture of drug and excipients were recorded by KBr method using Fourier Transform Infrared Spectrophotometer. A base line correction was made using dried potassium bromide pellet. The potassium bromide-drug pellet of approximately 1 mm diameter, was prepared by grinding 3-5 mg of physical mixture of drug-excipients with 100-150 mg of potassium bromide in pressure compression machine. The sample pellet was mounted in IR compartment and scanned at wavelengths 4000 cm⁻¹ to 400 cm⁻¹.

Determination of λ_{max} of Deflazacort:

Accurately weighed 10 mg of drug was dissolved in 100 ml of phosphate buffer pH 7.2 in a 100 ml volumetric flask. 0.1 ml of this stock solution was pipetted into a 10 ml volumetric flask and volume was made up to the mark with phosphate buffer pH 7.2. The resulting solution was scanned between 200-400 nm using UV/Vis double beam spectrophotometer. The same procedure was followed for determining the wavelength maxima phosphate buffer pH 7.2.

Fabrication of Deflazacort loaded nanoparticles by ionic gelation technique:

Chitosan nanoparticles were prepared by Ionic gelation method. Chitosan stock solution (1% w/v) was prepared by dissolving chitosan in acetic acid (1% v/v) in a beaker at room temperature. The 5mg of drug Deflazacort was dissolved in chitosan solution in a beaker for around five minutes with the help of a bath sonicator (Indian Machine tools, India). STPP solution (1%) was prepared separately in distilled water. Chitosan nanoparticles were fabricated with the dropwise addition of STPP solution with the help of a syringe to chitosan solution under magnetic stirring at room temperature. The solution was magnetically stirred for half an hour followed by filtration and rinsing with distilled water. The acquired Nanoparticles were air dried for twenty four hours followed by oven drying for six hours at 40°C ^[12]. The composition of chitosan nanoparticles is given (Table 1).

Coating of prepared nanoparticles:

With the aid of solvent evaporation method, chitosan nanoparticles were coated with Eudragit S-100 (ES). In 10ml of the coating solution prepared by dissolving 500 mg of ES-100 in ethanol, 50 mg of nanoparticles were dispersed: acetone (2:1) to give 5:1 (coat: core ratio). Subsequently, this organic process was poured in light liquid paraffin containing 1% w/v

Table 1: Formulations of chitosan nanoparticles.

Formulation Code	Deflazacort (mg)	Chitosan (mg)	STPP (mg)
F1	5	250	500
F2	5	250	750
F3	5	250	1000
F4	5	500	500
F5	5	500	750
F6	5	500	1000

Span 80. The system was maintained for 3 hours at room temperature under agitation speed of 1000 rpm which allows the solvent to evaporate. The coated nanoparticles coating were filtered, washed with n-hexane and dried in desiccators^[13].

Evaluation of nanoparticles:

Drug Entrapment Efficiency-

Deflazacort was estimated in Chitosan nanoparticles by ultra centrifugation method. The 10mg of formulation was transferred to 10 ml centrifuge tube and diluted with distilled 10 ml of phosphate buffer (pH 7.2) and centrifuged at 2000 rpm for 20 minutes to separate out undissolved drug in the formulation. Supernatant and nanoparticles (sediment) was recovered and their volume was measured. Nanoparticles was diluted with distilled water upto 5ml. The untrapped and entrapped drug contents were analyzed by estimating drug in supernatant and nanoparticles by spectroscopic method. The percentage of drug entrapment and yield was calculated as:

% drug entrapment = calculated drug content / theoretical drug content $\times 100$

Measurement of mean particle size-

The mean particle size of the nanoparticles was determined by Photo Correlation Spectroscopy (PCS) on a submicron particle size analyzer (Malvern particle size analyzer) at a scattering angle of 90°. A sample (0.5mg) of the nanoparticles was dragged in 5 ml of distilled water which was used for the measurement.

Determination of zeta potential-

The zeta potential of the drug-loaded nanoparticles was measured on a zeta sizer (Malvern particle size analyser) by determining the electrophoretic mobility in a micro electrophoresis flow cell. All the samples were measured in water at 25°C in triplicate.

Shape and surface morphology-

From the formulated batches of nanoparticles, formulations (F2) which exhibited an appropriate balance between the percentage of drug releases was examined for shape and surface morphology with the help of a scanning electron microscope (Jeol Japan 6000). The Sample was fixed on carbon tape and fine gold sputtering was applied in a high vacuum evaporator. The acceleration voltage was set at 10KV during scanning. Microphotographs were taken on different magnification and higher magnification (200X) was used for surface morphology.

In-Vitro Drug Release-

The prepared nanoparticles were evaluated for in vitro drug release by using USP I Basket type dissolution test apparatus. An accurately weighed quantity of formulation (equivalent to 30mg) was filled in capsule and kept in the basket of dissolution apparatus with the dissolution media (900 ml) at 37 \pm 0.2°C. Samples were withdrawn at a different time interval and compensated with same amount of fresh dissolution media. The Volume of sample withdrawn was made up to 5ml by dissolution media. The samples withdrawn were assayed spectrophotometrically at 242 nm for percentage release of Deflazacort using UV visible spectrophotometer. The release of Deflazacort was calculated with the help of a standard curve of Deflazacort. The scheme of using the simulated fluids at different timing was as follows:

1st hour: Simulated gastric fluid (SGF) of pH 1.2.

2nd and 3rd hour: Mixture of simulated gastric and

Intestinal fluid of pH 4.5.

4th to 5th hour: Simulated intestinal fluid (SIF) of pH 6.8

6th hour and onward: SIF pH 7.5

Drug release kinetic data analysis-

Several kinetic models have been proposed to describe the release characteristics of a drug from the matrix. The following four equations are commonly used, because of their simplicity and applicability. Equation 1, the zero-order model equation (Plotted as cumulative percentage of drug released vs time); Equation 2, the first-order model equation (Plotted as log cumulative percent Drug remaining Vs time); Equation 3, Higuchi's square-root equation (Plotted as cumulative percentage of drug released vs square root of time); and Equation 4, the Korsmeyer-Peppas equation (Plotted as Log cumulative percentage of drug released vs Log time).

Stability studies for optimized formulation-

Stability of a formulation on storage is of great concern as it is the major restraint in their development as marketed preparation. Optimized nanoparticle formulation (F2) were stored in amber colored bottles thus subjected to exhaustive stability testing at $4 \pm 1^\circ\text{C}$ and room temperature for 3 month period. Samples were withdrawn periodically and formulation was observed on the basis of % EE, average particle size and physical appearance.

RESULTS & DISCUSSION:

Deflazacort was freely soluble in ethanol, methanol, 0.1 N NaOH & phosphate buffer pH 7.2. and practically insoluble in 0.1 N HCl, distilled water. Identification of Deflazacort was concluded by FTIR spectroscopy with respect to marker compound. It was identified from the result of IR spectrum as per specification in (Figure 1). The calibration curve of Deflazacort was found to be linear in the concentration range of 10-30 $\mu\text{g/ml}$ at 242 nm (Figure 2).

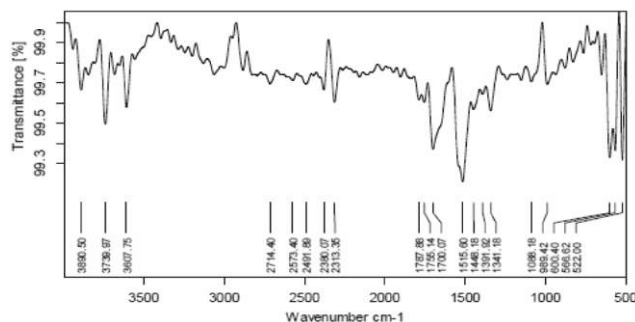


Figure 1: FT-IR Spectrum of Pure Drug (Deflazacort).

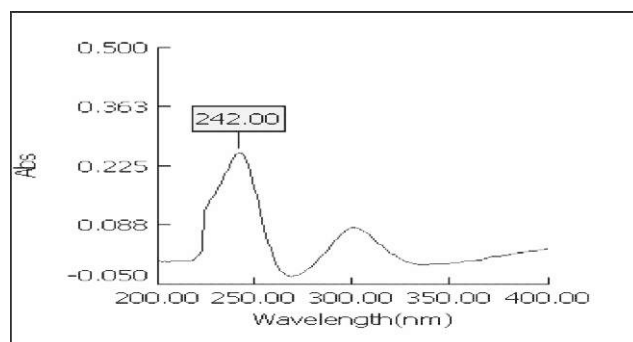


Figure 2: Wavelength maxima of Deflazacort in phosphate buffer pH 7.2

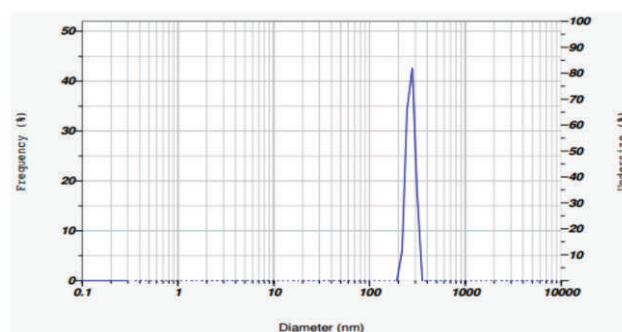
Percentage yield of the different formulation was determined by weighing the nanoparticles after drying. The percentage yield of the different formulation was in the range of 68.89-75.65%. The drug entrapment of different formulations was in the range of 63.23-73.23% w/w. This is due to the mucoadhesion characteristics of chitosan that could

facilitate the diffusion of part of entrapped drug to the surrounding medium during the preparation of Deflazacort nanoparticles. The maximum percentage yield and entrapment efficiency were found in formulation F2 (Table 2).

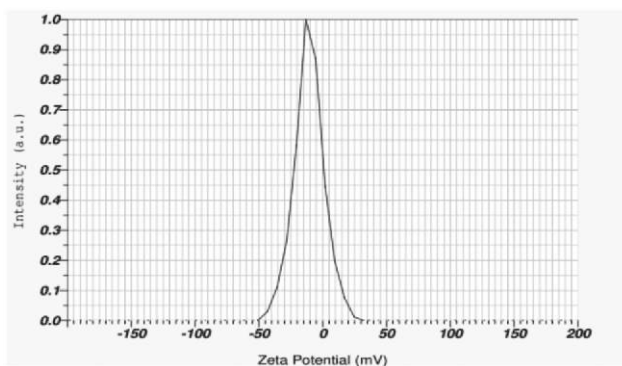
Table 2: Percentage yield and Entrapment efficiency for different formulation.

Formulation	% Percentage Yield	% EE of Nanoparticles
F ₁	72.25 \pm 0.45	65.56 \pm 0.32
F ₂	75.65 \pm 0.32	73.23 \pm 0.45
F ₃	69.98 \pm 0.52	70.12 \pm 0.45
F ₄	69.45 \pm 0.65	68.85 \pm 0.65
F ₅	68.89 \pm 0.12	65.45 \pm 0.56
F ₆	70.12 \pm 0.54	63.23 \pm 0.41

The mean size of the nanoparticles was determined by photo correlation spectroscopy (PCS) on a submicron particle size analyzer (Particle Size Analyzer from Malvern) at a scattering angle of 90°C . The results of measurement of mean particle size of optimized formulation F2 nanoparticles were found 110.23 nm and zeta potential of optimized formulation F2 nanoparticles was found to be -30.5 mV (Figure 3).



(A)



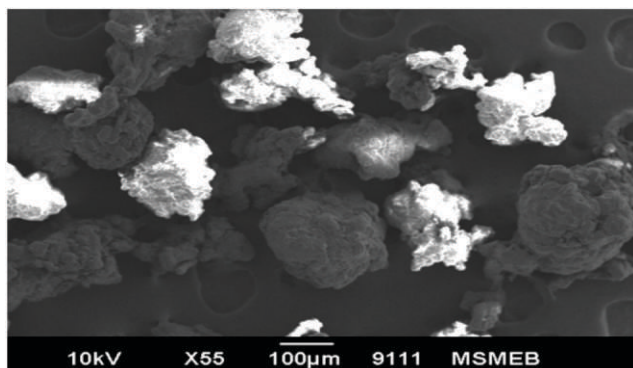
(B)

Figure 3: Particle size (A) Zeta potential (B) of chitosan nanoparticle (F2).

Table 3: Cumulative % drug release of Deflazacort from plain and eudragit S100 coated nanoparticles at different pH.

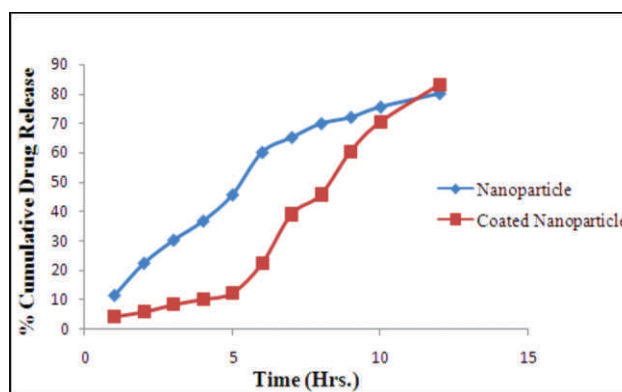
S. No.	Dissolution medium	Time (hrs)	% Cumulative Drug Release	
			Chitosan Nanoparticle	Eudragit S100 Coated Nanoparticle
1	SGF (pH 1.2)	1	11.25	4.12
2		2	22.25	5.65
3		3	30.12	8.15
4	SGF+SIF(pH 4.5)	4	36.65	9.95
5		5	45.65	12.12
6		6	60.12	22.12
7	SIF (pH 6.8)	7	65.23	38.89
8		8	69.98	45.65
9	SIF (pH 7.5)	9	72.12	60.23
10		10	75.65	70.23
11		12	80.23	82.98

The SEM photomicrographs of the chitosan nanoparticles were taken and characterized in terms of sphericity and particles clumping. As observed in photomicrograph the nanoparticles having a smooth surface and perfectly spherical (Figure 4).

**Figure 4:** Scanning Electronic Microscopy of optimized formulation (F2).

An *In-vitro* dissolution study was conducted to study the *in-vitro* drug release profile of plain and coated nanoparticle. As the purpose of this formulation was to avoid the release of drug in the gastric and upper intestinal region but to release the drug slowly in the lower part of the intestine maximizing drug concentration in the colon, the *in-vitro* drug release study was conducted at different pH using USP protocol. The obtained results are shown in (Tables 3) while presented in Figure 5 respectively.

The fabricated chitosan nanoparticles were subjected to the study of drug release kinetics and

**Figure 5:** Graph of cumulative % drug release of deflazacort from chitosan and eudragit S100 coated nanoparticles.

release mechanism. The *in-vitro* release data for optimized formulations F2 was analyzed for zero order, Higuchi and Korsmeyer-Peppas models. Based on the correlation co-efficient (r^2) best fitted model was selected (Table 4).

The average particle size of nanoparticle was found 110.23 ± 0.23 , 118.56 ± 0.36 and 135.65 ± 0.32 nm after 1, 2 and 3 month of storage at $4.0 \pm 0.2^\circ\text{C}$ while at $25-28 \pm 2^\circ\text{C}$ the average vesicle size was found 125.32 ± 0.45 , 145.65 ± 0.45 and 186.65 ± 0.54 nm after 1, 2 and 3 month of storage. % EE in nanoparticle formulation was 65.56 ± 0.32 , 60.54 ± 0.36 and $55.65 \pm 0.56\%$ after 1, 2 and 3 month of storage at $25-28 \pm 2^\circ\text{C}$ while there were no significant changes in % EE and physical appearance in nanoparticle formulation was observed after 3 month of storage at 4°C (Table 5).

Table 4: Regression Analysis Data of nanoparticle Formulation.

Formulation	Zero order	First order	Pappas plot
F2	$y = 7.644x - 14.33$ $R^2 = 0.905$	$y = -0.053x + 2.126$ $R^2 = 0.841$	$y = 1.316x + 0.394$ $R^2 = 0.885$

Table 5: Characterization of stability study of Optimized formulation of nanoparticle F2.

Characteristic	Time (Month)					
	1 Month		2 Month		3 Month	
Temperature	4.0 ±0. 2°C	25-28±2°C	4.0 ±0. 2°C	25-28±0. 2°C	4.0 ±0. 2°C	25-28±2°C
Average particle size (nm)	110.23 ±0.23	125.32 ±0.45	118.56 ±0.36	145.65 ±0.45	135.65 ±0.32	186.65 ±0.54
% EE	73.23 ±0.23	65.56 ±0.32	71.45 ±0.54	60.54 ±0.36	69.98 ±0.45	55.65 ±0.56
Physical Appearance	Normal	Normal	Normal	Normal	Normal	Normal

CONCLUSION:

The data generated as an outcome of this article demonstrates that the stable colon targeted Eudragit S-100 coated deflazacort nanoparticles with chitosan for the treatment of IBD was developed. The successful preparation of nanoparticles was established by characterization analysis. The maximum percentage yield and drug content was found 75.65±0.32 and 73.23±0.45 respectively in formulation F2. The lowest particle size entrapped the higher drug content as compared to the other formulations. Also *in vitro* studies of uncoated and eudragit S100 coated nanoparticles was carried out in simulated gastrointestinal fluid medium of different pH. Cumulative percentage drug released was found from various optimized formulation at different time intervals. In case of chitosan coated nanoparticles nearly 36.65–45.65% of the drug released in initial 4–5 h. This situation is best suited in condition where drug is required to be absorbed or remain in the upper part of GIT. As far as treatment of colonic disease is concerned, it is important to ensure the delivery of drug in intact form in the vicinity of target organ.

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Primary Ovarian Pregnancy – A Rare Case Report

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ABSTRACT

A pregnancy confined to ovary accounts for upto 3% of all ectopic pregnancy and is the most common type of nontubal ectopic pregnancy. Ovarian ectopic can present as atypical presentation such as adnexal mass. A 26yr old female G4P2L1A1 presented in Gynaecology OPD with chronic dull aching generalized abdominal pain on and off since 5 months. Occasionally pain would radiate to the right shoulder. There was no history of amenorrhoea, syncopal attack and her menstrual cycles were normal. Patient was admitted and all necessary and emergency investigations were carried out. An ovarian ectopic pregnancy was found (fulfilling the Spiegelberg criteria) after exploratory laparotomy was performed.

KEY WORDS: adnexal mass, ectopic, ovarian, spiegelberg

INTRODUCTION:

A Pregnancy confined to the ovary accounts for upto 3% of all ectopic pregnancy and is the most common type of non tubal ectopic pregnancy. Unruptured ovarian ectopic is rare and is diagnosed if four clinical criteria are fulfilled outlined by Spiegelberg: 1) Ipsilateral tube is intact and distinct from the ovary; 2) Ectopic pregnancy occupies the ovary; 3) Ectopic pregnancy is connected by the utero-ovarian ligament to the uterus and 4) Ovarian tissue can be demonstrated histologically amid placental tissue.

11 per 1000 pregnancies are ectopic out of which 95% are tubal and 5% are Non tubal. Non tubal ectopic pregnancy is very rare but potentially life threatening. It is often misdiagnosed and can have rare presentations.

CASE REPORT:

A 26yr old female G4P2L1A1 presented in Gynaecology OPD with chronic dull aching generalized abdominal pain on and off since 5 months. Occasionally pain would radiate to the right shoulder. There was no history of amenorrhoea, no history of syncopal attack and her menstrual cycles were normal. Patient gave history of intake of unsupervised MTP

pills since past 5 months at the gestation period of 6 weeks. She gave history of suction and evacuation done at some private setup for uncontrolled bleeding, however no records or ultrasound report were available. After suction and evacuation patient stopped bleeding and resumed her regular menses.

On admission at our hospital, patient was clinically and haemodynamically stable. Per Abdomen Examination-Vague discomfort was felt on whole abdomen. Per Speculum Examination- Cervix grossly normal. Per Vaginal Examination- Uterus anteverted, normal size, mobile, an irregular mass of approximately size 4.3cm felt in the posterior fornix tender and fixed, no cervical motion & tenderness (Figure 3 & 4).

Investigations:

UPT – Positive, Hb-7.9g/dl, Beta HCG- 271.60mIU/ml, CA-125-114.40U/ml. Ultrasonography – Heterogenous solid cystic mass lesion seen closely adherent to right ovary of size 5.5*2.8cm showing mild vascularity.

Hospital Course and Management:

After taking written and informed consent and blood arranged, patient was taken for exploratory laparotomy. There was intact pregnancy sac in the right ovarian fossa which was in the process of expulsion (Figure 1). Uterus and both tubes were normal and away from the mass. Gestational sac over the ovary, was removed gently (Figure 2). Corpus Luteum was on right ovary itself with bleeding surface. Haemostatic sutures were applied to the site (Figure 3). Few blood clots of 150 ml were removed from Pouch of Douglas. Post

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Figure1: Showing Intact sac in process of Expulsion.



Figure 2: Intact Bi lateral tubes and ovaries.

operatively single unit of blood was transfused. Patient. withstood procedure well. Histopathology report suggests Chorionic villi within the ovarian stroma suggestive of an ovarian pregnancy (Figure 4).

DISCUSSION:

Ovarian pregnancy is a rare variant of ectopic pregnancy and can have rare presentation of Adnexal mass. Early diagnosis of ovarian pregnancy is necessary in order to avoid more serious complications



Figure 3: Hemostatic suture applied over ovary.

and emergency invasive procedures.

However, preoperative diagnosis remains challenging. Its diagnosis is difficult and relies on criteria based on intraoperative findings and histopathology report. Its management remains surgical therapy despite the progress in medical treatment.

CONCLUSION:

High Index of suspicion of ectopic pregnancy should be there in women of reproductive age group presenting with amenorrhoea. Safe abortion practices

to be encouraged and confirmation of location of gestation should be done prior to prescribing medical abortion.

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Figure 4: Intact Gestational sac.

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